PETITION

To the State Health Coordinating Council
Related to Mobile PET Services for
The 2015 State Medical Facilities Plan

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Statement of the Requested Change:

Novant Health and MedQuest recommend the following change related to mobile PET scanners in Chapter 9 of the 2015 SMFP:

- Establish a 2015 SMFP health-planning based policy that allows existing hospital providers who own and operate more than one CON-approved fixed PET/CT scanner, for a one year filing period during the 2015 SMFP plan year (1/1/2015-12/31/2015), to seek approval to convert one of their existing fixed PET/CT scanners to a mobile PET/CT scanner through the replacement equipment provision identified at N.C. Gen. Stat. §131E-176(22a).

- Replace the mobile East & West mobile PET/CT service areas defined in current SMFPs with a mobile PET service area that includes the entire state of North Carolina for the 2015 SMFP plan year and beyond to permit all mobile PET/CT scanners including the existing mobile PET provider and any subsequent providers to serve all of North Carolina. The creation of a process to expand mobile PET capacity in North Carolina is of primary importance to the petitioner. However, the petitioner also believes that the East/West mobile PET service area definitions have outlived their usefulness. Enhanced choice and competition will be created if hospitals seeking to add mobile PET services or expand their days of mobile PET service will more readily be able to obtain at least two competing proposals when there is more than a single mobile PET vendor able to offer mobile services across all of North Carolina. The abolition of the east/west mobile PET scanner service area would benefit both the existing mobile PET vendor and future mobile PET vendors. And equally as important is that mobile PET customers would also benefit.

The proposed language for a new **2015 SMFP Policy AC-7: Conversion of Existing Fixed PET/CT Scanners to Mobile PET/CT Scanners** is:

1. **Licensed North Carolina acute care hospitals that own and operate more than one CON-approved fixed PET/CT scanner may, for a one year period during the 2015 SMFP plan year (1/1/2015-12/31/2015), seek CON approval to convert one of their existing PET/CT scanners to a mobile PET/CT scanner through the replacement equipment provision identified at N.C. Gen. Stat. §131E-176(22a).**

2. **Beginning with the 2015 SMFP plan year, the East and West mobile PET/CT Scanner service areas will be eliminated and the new mobile PET/CT scanner service area will include entire state of North Carolina, such that the single existing mobile PET/CT scanner vendor as of CY 2014 and all subsequent mobile PET/CT scanner providers can be permitted to serve mobile PET/CT scanner host sites in any of the 100 counties in North Carolina.**

Background

There are currently only two (2) mobile PET/CT scanners in North Carolina and those two (2) mobile PET scanners provide service to 29 mobile PET host sites[1]. The original need determinations for mobile PET/CT scanners were generated, over 12 years ago, in the 2002 State Medical Facilities Plan, which divided North Carolina into two mobile PET service regions. The West Region service area consists of Health Service Areas I, II and III with over 5.17 million residents in 2013. The East Region service area consists of Health Service Areas IV, V and VI with over 4.8 million residents. The last CON for a mobile PET scanner in the West Region was awarded in 2003 (Project I.D. No. F-6605-02). The last CON for a mobile PET scanner in the Eastern Region was awarded in 2003 (Project I.D. No. H-6706-02). Both mobile PET scanners have been owned and operated by one sole provider, Alliance Imaging since that time.

Since the 2002 SMFP need determination for the two mobile PET scanners, there have been no subsequent need determinations for new mobile PET scanners despite significant growth in volumes and the number of mobile host sites served as detailed in the following chart. The existing two (2) mobile PET units owned and operated by Alliance Imaging serve a combined 29 host sites across the entire state of North Carolina.

Certain health systems in North Carolina with robust cancer treatment programs and more than one fixed PET/CT scanner also have contracts with Alliance Imaging to provide mobile PET/CT scan services at health system hospitals. For several years, Novant Health has had a service agreement with Alliance Imaging to provide mobile PET/CT services to four Novant Health hospital sites located in Health Service Areas II and III: (1) Novant Health Thomasville Medical Center, Thomasville, NC (Davidson County)-HSA II; (2) Novant Health Rowan Medical Center, Salisbury, NC (Rowan County)-HSA III; (3) Novant Health Huntersville Medical Center, Huntersville, NC (Mecklenburg County)-HSA III; and (4) Novant Health Matthews Medical Center, Matthews, NC

[1] The number of active mobile PET host sites identified in Alliance Imaging's January 2014 Registration and Inventory of Medical Equipment Mobile Positron Emission Tomography Scanners. See **Attachment 1** for copies of the reports.

(Mecklenburg County)-HSA III. Three of these four mobile PET host sites have or will have within the next year radiation therapy service provided by an on campus linear accelerator. The most common use of PET/CT scan imaging in North Carolina continues to be cancer diagnosis and treatment monitoring.

During the most recent year, FFY 2013, these four mobile PET host sites at Novant Health's acute care hospitals have collectively performed 675 mobile PET/CT scans based on 1 to 3 days per month that the mobile PET scanner is contracted and available to be at each of the four host sites. Each of these four mobile PET sites has demonstrated that it is financially feasible. In addition, each site provides 65-83% of its PET/CT scans to medically underserved populations defined to include Medicaid, Medicare, and Charity Care/Self-Pay. In addition, should the 2015 SMFP be modified to permit the conversion of fixed PET scanners to mobile PET/CT scanners, Novant Health anticipates that its potential future mobile PET/CT scanner could also seek to serve other sites, such as: (5) Kernersville Medical Center, which has a satellite cancer program on campus, including a linear accelerator, chemotherapy program, medical and surgical cancer physicians, cancer nurse navigators, and nutritionists; or (6) Novant Health Franklin Medical Center, Louisburg, NC (Franklin County)-HSA IV, where there is also a freestanding linear accelerator in Louisburg.

Alliance Imaging Eastern Region – Mobile PET

During FFY 2010-11, FFY 2011-12, and FFY 2012-13, the Alliance Imaging Eastern Region mobile PET scanner exceeded 2,600 procedures, which is defined in the 2014 SMFP, Chapter 9, Tables M(1) & (2) at page 143 as the annual capacity of a mobile PET unit, regardless of the number of host sites served. The number of host sites has increased from eight sites during FY 2003-04 to eleven sites in FFY 2012-2013.

Alliance Imaging Eastern North Carolina – Historical Mobile PET Utilization

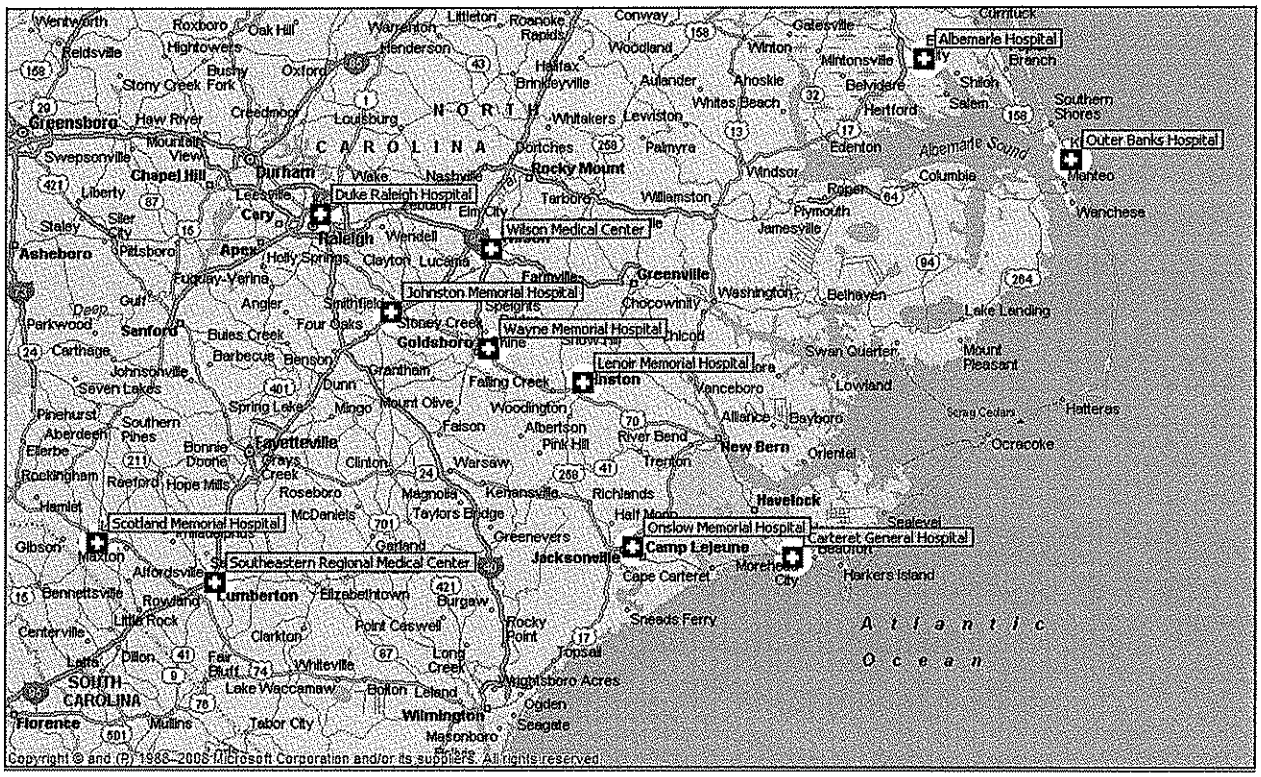
SMFP*	Data Year	No. of Host Sites*	PET volume	% Change
2006	FFY 2004	8	1,094	----
2007	FFY2005	8	2,175	98.8%
2008	FFY 2006	7	1,543	-29.0%
2009	FFY 2007	7	2,036	32.0%
2010	FFY 2008	8	2,619	28.6%
2011	FFY2009	9	2,437	-6.9%
2012	FFY2010	10	2,550	4.6%
2013	FFY 2011	11	**2,650**	3.9%
2014	FFY 2012	11	**2,811**	6.1%
2015	FFY 2013	11	**2,858**	1.67%

*No. of host sites is based on sites reported in each SMFP that performed 1 or more scans. Data for FFY 2013 obtained from the Registration and Inventory of Medical Equipment Mobile Positron Emission Tomography Scanners January 2014 filed by Alliance Imaging. *NOTE: SMFP Year 2012, for example, is based on FFY 2010 data.

Only **one** piece of Alliance Imaging mobile PET equipment serves all of the 11 host sites in the Eastern Region, as shown on the map below. The distance from Scotland Memorial to the Outer Banks Hospital is nearly 300 miles. The Eastern Region mobile PET unit covers an area encompassing approximately 18,000 square miles of eastern North Carolina, which is home to 4.8 million residents.

The following map identifies the Eastern Region Alliance Imaging mobile PET host sites.

Alliance Imaging Eastern Region – Mobile PET Host Sites



Alliance Imaging Western Region – Mobile PET

In every reporting year since FY 2006-07 (2009 SMFP), the Western Region mobile PET scanner has exceeded 2,600 procedures. The number of host sites has dramatically increased from 7 sites during FY 2003-04 to 18 sites in FY 2012-2013.

Alliance Imaging Western North Carolina – Historical Mobile PET Utilization

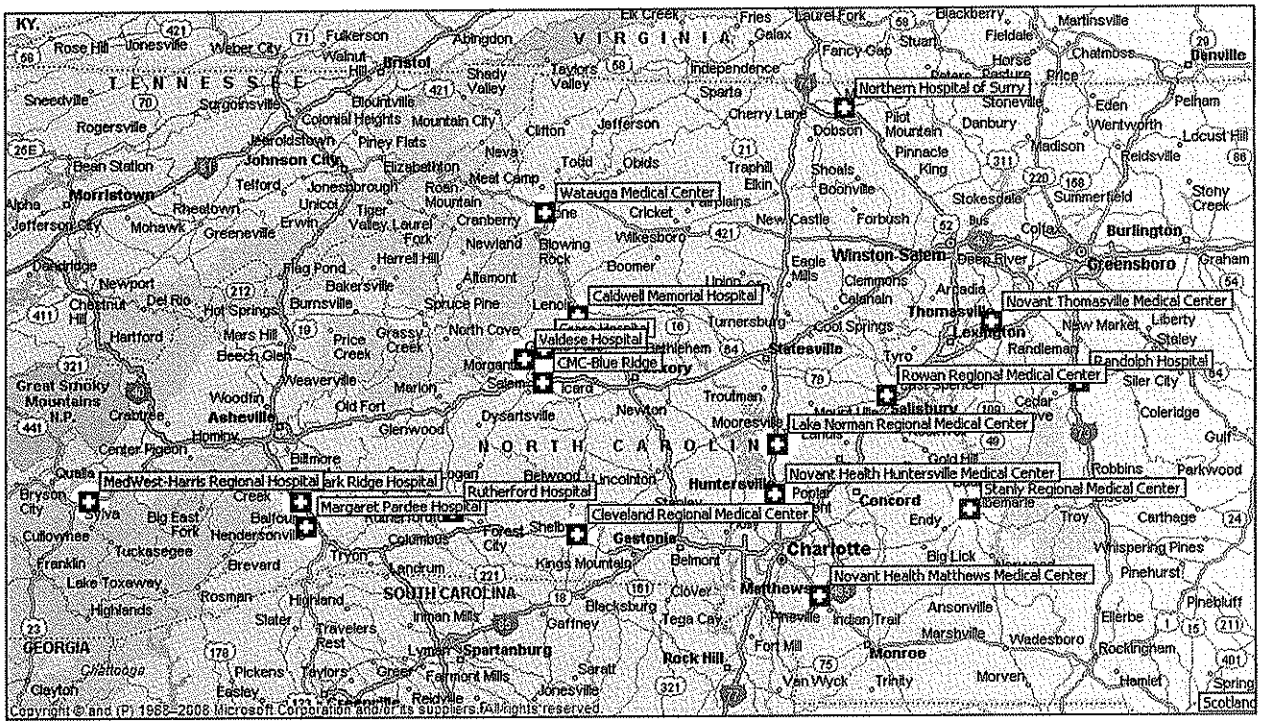
SMFP	Data Year	No. of Host Sites*	PET volume	% Change
2006	FFY 2004	7	1,154	----
2007	FFY2005	8	1,446	25.3%
2008	FFY 2006	13	1,885	30.3%
2009	FFY 2007	14	**2,826**	49.9%
2010	FFY 2008	15	**3,196**	13.1%
2011	FFY2009	14	**2,821**	-11.7%
2012	FFY2010	18	**2,861**	1.4%
2013	FFY 2011	18	**3,066**	7.2%
2014	FFY 2012	19	**3,066**	2.3%
2015	FFY 2013	18^	**2,933**	-4.3%

*No. of host sites is based on sites reported in each SMFP that performed 1 or more scans.
^CMC-Union now operates a fixed PET/CT scanner.

Only **one** piece of mobile PET equipment serves all of the 18 host sites in the Western Region. From the furthest points east (Randolph Hospital) and west (WestCare Health System formerly MedWest Harris), the Western Region mobile PET scanner covers a distance of over 200 miles. The Western Region mobile PET unit covers an area encompassing approximately 21,000 square miles of western North Carolina, which is home to 5.17 million residents.

The following map identifies the Western Region Alliance Imaging mobile PET host sites.

Alliance Imaging Western Mobile PET Host Sites



Alliance Imaging Mobile PET Services at Novant Health Facilities

Of all the vast number of host sites served by the sole mobile PET scanner in the Western Region, Novant Health operates four of these sites: Novant Health Thomasville Medical Center, Novant Health Rowan Medical Center, Novant Health Huntersville Medical Center, and Novant Health Matthews Medical Center. The following chart details the current schedule for mobile PET services for each of these Novant Health facilities.

Novant Health – Western Region Mobile PET Host Sites

Mobile PET Host Site	Current Monthly Mobile PET Service Days
Novant Health Thomasville Medical Center	**Every Other Tuesday (Half Day-2:30-8:00 pm)**
Novant Health Rowan Medical Center	**Every Other Thurs (Full Days-7 am-10pm)** **Every Other Thurs (Half Days-2-6pm)**
Novant Health Huntersville Medical Center	**One Monday per month (Full Day-7am-10pm)** **Every Other Thursday (Half Day-2:30-8:00pm)**
Novant Health Matthews Medical Center	**One Monday Per Month (Half Day-2:30-8:00pm)** **One Friday Per Month (Half Day-2:30 -8:00pm)***

Source: Current Alliance HealthCare Services-Novant Health mobile PET service contract.
*NOTE: Recently adjusted mobile PET schedule at Novant Health Matthews Medical Center to every other Friday for half days.

Novant Health currently contracts with Alliance Imaging for mobile PET service at these host sites. Over the past several years, Alliance representatives have told Novant that additional days of service are not available due to the number of sites being serviced. Based on input from hospital representatives, the following are some of the facility-specific issues:

Novant Health Thomasville Medical Center – Patients are having difficulty getting PET procedures scheduled and must travel to other facilities; additional mobile PET time has been requested and is not available; there have been some instances of downtime or delays that have resulted in the mobile PET service not being available during its scheduled time.

Novant Health Rowan Medical Center – Patients are having difficulty getting PET procedures scheduled and must travel to other facilities in Charlotte or Winston-Salem; physicians in Rowan County are unhappy with the lack of more accessible mobile PET service and the need to send patients to other health systems for imaging; additional mobile PET time has been requested and is not available.

Novant Health Huntersville Medical Center– Patients are having difficulty getting PET procedures scheduled and must travel to other facilities; additional mobile PET time has been requested and is not available; patients have had to be rescheduled due to equipment failure; one instance of the mobile PET unit being taken to the wrong facility which required NHHMC's patients to be rescheduled.

Novant Health Matthews Medical Center– Patients are having difficulty getting PET procedures scheduled and must travel to other facilities; additional mobile PET time has been requested and is not available.

See **Attachment 2** for letters of support from Presidents of Novant Health acute care hospitals that currently have contracted mobile PET/CT services (NHRMC, NHHMC, NHMMC, and NHTMC) or who wish to add mobile PET/CT services in the future (Novant Health Kernersville Medical Center). These support letters are signed by the hospital Presidents on behalf of each medical center and the cancer physicians who practice there.

Novant Health Rowan Medical Center has a busy and well-established cancer treatment program in radiation therapy. Professional coverage for the care of RRMC cancer patients is provided by the board-certified medical oncologists at Carolina Oncology Associates, with an office based in Salisbury near Rowan Regional Medical Center and by radiation oncologists associated with Southeastern Radiation Oncology Group, P.A., radiation oncologist practicing in Salisbury See the NHRMC President's support letter found in **Attachment 2.** NHRMC currently offers radiation therapy treatments on its linear accelerator and radiation therapy treatment planning services on its CT simulator, which are located in a freestanding facility on Henderson St. in Salisbury, near the hospital. During FFY 2013, as reported in the NHRMC 2014 annual Hospital Licensure Renewal Application, NHRMC performed 7,615 radiation therapy treatments for 246 cancer patients. In FFY 2012 as reported on the NHRMC 2013 hospital licensure renewal application, NHRMC performed 8,138 radiation therapy treatments for 302 cancer patients.

During FFY 2013 as reported in the **Novant Health Thomasville Medical Center's** 2014 Hospital Licensure Renewal Application, NHTMC was only able to perform 98 PET scans for as the Alliance Imaging mobile PET/CT scanner is only on site at NHTMC every other Tuesday for a half day. The AI mobile PET scanner is contracted to be at the TMC host site for 5.5 hours every other Tuesday. The medical oncology group, Piedmont Hematology Oncology Associates (POHA) has a busy satellite office in Davidson County, between Lexington and Thomasville (near the edge of Thomasville), where they offer medical and gyn oncology services, as well as chemotherapy on site. As noted in the Novant Health Thomasville Medical Center letter of support, PHOA physicians believe that 11 to 16.5 hours per month of available mobile PET scan time is insufficient and results in too many PHOA patients being unable to have their PET/CT scan performed conveniently in Davidson County. The alternatives are to travel to Winston-Salem, Greensboro, High Point, or Charlotte.

During that same time period (FFY 2013), **Novant Health Huntersville Medical Center** was able to perform 201 PET scans on the AI mobile PET scanner hosted at NHHMC for every other Thursday (Half days of 5.5 hours) and one Monday per month (Full day for 15 hours). Novant Heath Huntersville Medical Center offers a dedicated Breast Imaging Center for its patients. In addition, there are five medical oncologists are on the active medical staff at Novant Heath Huntersville Medical Center. The two medical oncology groups that provide medical oncology care for PHH's patients are: Southern Oncology Specialists with offices in Huntersville and the Mallard Creek area of Charlotte and Lake Norman Hematology Oncology with offices in Huntersville and Mooresville. See **Attachment 2** for a letter of support from Novant Health Huntersville Medical Center including feedback from the NHHMC President on behalf of the hospital and the cancer specialty physicians who practice there. In addition, Novant Health was recently approved by a DHSR Declaratory Ruling[2] to develop a previously CON-approved linear accelerator (CON Project I.D. #F-7518-06) on

[2]See DHSR Declaratory Ruling dated 2/7/2014. See **Attachment 3** for a copy of the Declaratory Ruling.

the campus of Novant Health Huntersville Medical Center and that linear accelerator is currently slated to become operational during the first quarter of CY 2015. This will further expand the cancer services that NHHMC can offer locally on its campus and will increase the demand for enhanced access to mobile PET/CT diagnostic services on the NHHMC campus.

Also, during FFY 2013 **Novant Health Matthews Medical Center ("NHMMC")** performed 132 PET scans on the AI mobile PET scanner during the one Monday per month (Half day-5.5 hours) and every other Friday per month (Half day-5.5 hours) that it is on site at Matthews. Southeastern Radiation Oncology (SERO), a group of radiation oncologists, operates a linear accelerator in a medical office building located on the Novant Health Matthews Medical Center campus. In addition, professional coverage for cancer patients at PHMatthews is provided by the four medical oncologists and hematologists at Matthews Hematology Oncology Associates (MHOA). See **Attachment 2** for a letter of support from Novant Health Matthews Medical Center and its cancer physicians. The MHOA physicians also offer chemotherapy services at their office. The availability of the mobile PET at NHMMC for no more than16.5 hours per month is insufficient to permit routine local access to PET/CT scans that are an essential part of the care of cancer patients. Especially in light of the fact that the linear accelerator in the medical office building on the NHMMC campus is one of the single busiest linear accelerators in North Carolina on a year-in, year-out basis.

Action by the SHCC IS Necessary to Address the Need for Additional Mobile PET Scanner Choices and Capacity

The State Medical Facilities Plan (SMFP) fails to address need for additional mobile PET scanner capacity when an existing mobile PET scanner unit(s) exceeds the capacity threshold set forth in Table 9M(1) of the 2014 SMFP (page 141), in the column heading called "Utilization Rate: Year 2012 Procedures/2600 as Capacity." This is the annual capacity of one mobile PET/CT scanner regardless of the number of host sites serves during the year. It is not clear that the 2,600 PET scans per year was intended to be applied to the annual volumes at each mobile PET host site in a region[3], when each host site was only getting access to a fraction of the capacity of a single mobile PET unit, due to the vendor's schedule which allows most mobile PET sites an average of about 2 days per month of mobile PET service. In recent planning cycles, there have been three petitions submitted related to mobile PET scanners, all of which have been denied by the Technology & Equipment Committee and the State Health Coordinating Council[4]. The lack of formal need determinations for mobile PET scanners is creating unnecessary hardships for healthcare providers and patients and requires the action of the State Health Coordinating Council.

As previously stated herein, today the only two (2) mobile PET scanners in North Carolina exceed the 2,600 annual PET scan capacity threshold for a single mobile PET scanner as defined in the 2014 SMFP. Using the FFY 2013 mobile PET volumes reported in the Alliance Imaging 2014 Mobile

[3]As is done in Table 9M(2) of the 2013 SMFP, Chapter 9, page 160.

[4]In August 2010, Neo Pet, LLC submitted a petition requesting a special need determination for a mobile PET to serve the western region. Carolinas Medical Center filed a petition in March 2011 requesting a need determination for mobile PET scanners. Novant Health filed a mobile PET petition in March 2013 requesting a need determination for mobile PET scanners.

PET Equipment Inventory and Registration form, the Western Region Mobile PET was at 113% capacity and the Eastern Region was at 110% capacity **and realistically cannot increase further due to limitations on the number of sites a single unit can physically serve.** In the 2014 SMFP Table 9(M)(2), the capacity of 2,600 procedures per mobile host site is completely unreasonable and has no basis in actual daily operations. The majority of these mobile PET host sites have between 1 and 2 days of service per MONTH. Practically speaking, the ability of a mobile PET host site to reach 2,600 procedures with 12 to 24 days of service annually would require 108 to 217[5] PET procedures per day of service, which is logistically impossible.

Current Mobile PET Data Shows Need for Additional Mobile PET/CT Scanners

The 2014 Alliance Imaging Mobile PET Scanner Medical Equipment Inventory Reports, which is the basis for the data to be utilized in the 2015 SMFP shows the following:

a. The Eastern Region PET scanner performed a total of 2,858 procedures and provided service to over 11host sites. This mobile PET/CT scanner is operating at 110% of capacity (=2,858/2,600).
b. The Western Region PET scanner performed a total of 2,933 procedures and provided service to over 18 host sites. This mobile PET/CT scanner is operating at 113% of capacity (=2,933/2,600).

The utilization of the Alliance Imaging Western mobile PET/CT scanner has increased from 106.2% of capacity in FFY 2012 to 113% in FFY 2013. The utilization of the Alliance Imaging Eastern mobile PET/CT scanner has increased from 108.1% in FFY 2012 to 110% in FFY 2013.

This proposal suggests a method, via a new and time-limited SMFP Policy that permits the development of a modest amount of additional mobile PET scanner capacity by the conversion of existing previously-CON approved fixed PET scanners. This approach does not increase the total number of PET/CT scanners in North Carolina, but does serve the important purpose of allowing existing fixed PET/CT scanners to be re-deployed to a more productive future use as a mobile PET/CT scanner. Again, the only two (2) mobile PET scanners in North Carolina have exceeded the 2,600 procedure capacity. If corrective action is not taken now for the 2015 SMFP, this problem will continue to adversely affect North Carolina residents' access to mobile PET services.

As it stands, the State Medical Facilities Plan provides no method by which mobile PET scanner capacity can be enhanced or increased. In fact, since the 2003 SMFP each annual plan has explicitly stated that no additional mobile PET scanners were needed in North Carolina. In essence, there has been a moratorium on new mobile PET scanners since the 2003 SMFP. The threshold of 2,600 procedures annually has been surpassed by the two (2) existing Alliance Imaging mobile PET units in at least the last three data reporting periods[6]. By maintaining the status quo as it relates to mobile PET scanners, the citizens of North Carolina and their healthcare providers will continue to

[5] 2,600 procedures ÷ 12 days = 217 procedures/day of service; 2600 procedures ÷ 24 days = 108 procedures/day of service.

[6] The western mobile PET unit has performed more than 2,600 procedures since FFY 2007 (2009 SMFP). The eastern mobile PET unit has exceeded 2,600 procedures since FFY 2011 (2013 SMFP).

be limited to accessing only one mobile PET scanner for all of Eastern North Carolina and only one PET scanner for all of Western North Carolina. With a combined host sites total of 29 for only two (2) mobile PET scanners, this effectively means that on average, each host site can only access one day of service, one time per MONTH. In addition, considering the significant amount of travel time for these two mobile PET scanners, it is very likely that the equipment will require more downtime and maintenance, which could further adversely impact both cancer patients and healthcare providers seeking enhanced local access to the standard of care information (for diagnosis and treatment monitoring) provided by a PET/CT scan.

Suggested Changes for the Mobile PET Scanners

Novant Health and MedQuest recommend the following change related to mobile PET scanners in Chapter 9 of the 2015 SMFP:

- Establish a 2015 SMFP health-planning based policy that allows existing hospital providers who own and operate more than one CON-approved fixed PET/CT scanner, for a one year filing period during the 2015 SMFP plan year (1/1/2015-12/31/2015), to seek approval to convert one of their existing fixed PET/CT scanners to a mobile PET/CT scanner through the replacement equipment provision identified at N.C. Gen. Stat. §131E-176(22a).

- Replace the mobile East & West mobile PET/CT service areas defined in current SMFPs with a mobile PET service area that includes the entire state of North Carolina for the 2015 SMFP plan year and beyond to permit all mobile PET/CT scanners including the existing mobile PET provider and any subsequent providers to serve all of North Carolina. The creation of a process to expand mobile PET capacity in North Carolina is of primary importance to the petitioner. However, the petitioner also believes that the East/West mobile PET service area definitions have outlived their usefulness. Enhanced choice and competition will be created if hospitals seeking to add mobile PET services or expand their days of mobile PET service will more readily be able to obtain at least two competing proposals when there is more than a single mobile PET vendor able to offer mobile services across all of North Carolina.

The proposed language for a new **2015 SMFP Policy AC-7: Conversion of Existing Fixed PET/CT Scanners to Mobile PET/CT Scanners** is:

1. **Licensed North Carolina acute care hospitals that own and operate more than one CON-approved fixed PET/CT scanner may, for a one year period during the 2015 SMFP plan year (1/1/2015-12/31/2015), seek CON approval to convert one of their existing PET/CT scanners to a mobile PET/CT scanner through the replacement equipment provision identified at N.C. Gen. Stat. §131E-176(22a).**

2. **Beginning with the 2015 SMFP plan year, the East and West mobile PET/CT Scanner service areas will be eliminated and the new mobile PET/CT scanner service area will include entire state of North Carolina, such that the single existing mobile PET/CT scanner vendor as of CY 2014 and all subsequent mobile PET/CT scanner provider can be permitted to serve mobile PET/CT scanner host sites in any of the 100 counties in North Carolina.**

The creation of a statewide service area for mobile PET services will allow providers to more efficiently serve mobile host sites across the State. Currently, the East/West divide hampers the efficient provision of mobile PET service and no longer serves a valid health planning purpose. Mobile PET technology is highly specialized and should not be restricted to an east-west service area. For example, Randolph Hospital in Randolph County (HSA II) is literally on the line dividing the east and west mobile PET service. If a statewide service area was enacted, then mobile PET capacity could potentially increase for this facility assuming it was served by Alliance Imaging's eastern mobile PET unit, which has 11 host sites instead 18 sites on the western unit. In order to improve efficiency and optimize equipment performance, a statewide service area is the most logical option for this low inventory, highly specialized service.

The establishment of a conversion policy as a one-time opportunity for existing hospital fixed PET/CT scan providers (with multiple fixed PET/CT units) to establish mobile PET service is a unique and reasonable health planning-based solution for the following reasons:

A. The underutilization of fixed PET/CT scanners is a concern that has been raised during the discussions related to increasing the capacity of mobile PET scanners. The conversion of a fixed PET/CT unit to a mobile unit allows a hospital provider to increase the efficiency of this important diagnostic tool by utilizing it among several mobile host sites, instead of one fixed site, which creates enhanced local accessibility for cancer patients in their own communities.

B. The conversion policy will not result in a proliferation of mobile PET units as PET services in general are a technically complex service. A qualified hospital provider would need experience providing PET services as well as operational experience providing mobile health services.

C. By establishing the requirement that a provider has more than one fixed PET/CT scanner, it ensures that the conversion of a fixed PET unit to a mobile PET unit would not result in the elimination of fixed PET service from a county or service area.

D. The requirement that a hospital provider must have a CON-approved fixed PET scanner means that the hospital provider has already completed the rigorous CON

process and has satisfied all regulatory requirements for establishing PET service. There are only two rules related to mobile PET that would need to be addressed and both rules concern host site documentation[7]. The documentation, letters of intent with the mobile host sites and coordination with comprehensive cancer programs, requested by the rules could be required with the submission of the replacement equipment request.

Statement of Adverse Effects on the providers or consumers of health services that are likely to ensue if the change is not made.

PET Imaging Access for Medicare Patients & Other Medically Underserved Populations

According to a study[8] published in *Radiology* and conducted by researchers at Duke University and the University of North Carolina, Medicare beneficiaries with non-small cell lung cancer didn't receive equal access to PET scans, as fewer scans are done on patients who are older, African-American, or who live in less educated or economically advantaged areas of the country.

As shown in the mobile PET host site data for Thomasville Medical Center, Rowan Regional Medical Center, Presbyterian Hospital Huntersville, and Presbyterian Hospital Matthews, a large proportion of mobile PET services are accessed by Medicare recipients at these four mobile PET sites:

- At Novant Health Huntersville Medical Center, 63.3% of mobile PET/CT scans (133 of 210 PET/CT scans) were for Medicare patients in CY 2013
- At Novant Health Matthews Medical Center, 62.3% of mobile PET/CT scans (91 of 146 PET/CT scans) were for Medicare patients in CY 2013
- At Novant Health Rowan Medical Center (Salisbury, NC), 60% of mobile PET/CT scans (135 of 225 PET/CT scans) were for Medicare patients in CY 2013
- At Novant Health Thomasville Medical Center, of mobile PET/CT scans 69.2% (65 of 94 PET/CT scans) were for Medicare patients in CY 2013

The availability of mobile healthcare services, like PET imaging, at smaller community-based hospitals has a direct, positive impact on patients. One of the basic tenets of the certificate of need process is to provide accessibility to services for rural communities and underserved populations. N.C. Gen. Stat. §131E-175, states the following:

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[7] 10A NCAC 14C.3702(c) An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated.
10A NCAC 14C.3702(d) An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital to offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology.

[8] *Variations in Use of PET among Medicare Beneficiaries with Non-Small Cell Lung Cancer, 1998-2007.* Michaela Dinan, PhD, Lesley H. Curtis, PhD, William R. Carpenter, PhD, et al. See **Attachment 4.**

(3a) That access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process.

In addition to the consideration of the needs of rural communities, another vital component of the health planning process is the availability of services for the "underserved" populations[9]. The addition of a policy in the 2015 State Medical Facilities Plan to create a pathway for the reasonable expansion of mobile PET scanner capacity in North Carolina will certainly serve to expand access for medically underserved citizens of North Carolina to this important diagnostic service for underserved groups across North Carolina, including the Medicare populations depending on NHTMC, NHRMC, NHHMC, and NHMMC for local access to PET imaging, as discussed above.

Furthermore, based on CY 2013 data, these four Novant Health current mobile PET scanner sites served the following proportion of medically underserved patients with local access to PET/CT imaging:

- At Novant Health Huntersville Medical Center, 64.8% of mobile PET/CT scans (139 of 210 PET/CT scans) were for Medically Underserved patients in CY 2013
- At Novant Health Matthews Medical Center, 69.8% of mobile PET/CT scans (102 of 146 PET/CT scans) were for Medically Underserved patients in CY 2013
- At Novant Health Rowan Medical Center (Salisbury, NC), 72.0% of mobile PET/CT scans (149 of 225 PET/CT scans) were for Medically Underserved patients in CY 2013
- At Novant Health Thomasville Medical Center, 83.0% of mobile PET/CT scans (78 of 94 PET/CT scans) were for Medically Underserved patients in CY 2013

Local Access to PET Imaging for Cancer Patients

The availability of PET technology largely benefits cancer patients, although there are applications for patients with cardiac issues, lung cancer, and neurological diseases such as Alzheimer's. According to data from the State Center for Health Statistics, the number of projected **new** cancer cases in North Carolina continues to increase. See the chart below:

[9]Underserved populations are defined as low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. See N.C. Gen. Stat. §131E-183(3), commonly referred to as Review Criterion 3.

North Carolina Cancer Rates – Projected New Cancer Cases

Year	Projected New Cancer Cases	% Change
2004	39,815	----
2005	39,830	0.03%
2006	40,830	2.51%
2007	40,860	0.07%
2008	42,451	3.89%
2009	46,417	9.32%
2010	49,586	6.82%
2011	51,690	4.24%
2012	55,444	7.26%
2013	56,164	1.30%
2014	57,298	2.01%

Source: North Carolina State Center for Health Statistics. www.schs.state.nc.us/schs/CCR/projections.html

From 2004 to 2014, the annual number of new cancer cases in North Carolina has increased from 39,815 to 57,298 or nearly 44%. In a World Health Organization news release dated February 4, 2014, WHO called cancer "an imminent human disaster" with cancer cases expected to surge 57% worldwide in the next 20 years with cancer deaths rising from 8.2 million per year to 13 million during the same time period. As the number of cancer cases swell at a staggering rate, the availability of the tools utilized in the diagnosis and treatment of cancer are critical for the growing number of cancer patients. As further evidence in addressing this critical health issue, the Centers for Medicare & Medicaid Services ("CMS") has recently approved for coverage the use of up to three (3) PET scans per patient. See **Attachment 4** for both articles. Until now, the restricted reimbursement of PET imaging by third party payors has limited its use in clinical applications. With these new guidelines in place, health providers anticipate higher levels of utilization for PET imaging.

While residents in most large metropolitan areas have access to fixed PET sites[10], providers and hospitals in medium sized cities, smaller counties and rural areas rely almost exclusively on mobile PET service to offer enhanced accessibility to this important diagnostic tool for their residents. If mobile PET services are not available in a patient's home county, the patient would have to travel out of county or beyond in order to have access to these essential services. Below are examples of

[10]According to the 2014 SMFP at page 140, Table 9L there are 27 fixed PET scanners in NC located in large and mid-size cities and towns: Asheville, Burlington, Charlotte, Chapel Hill, Concord, Durham, Fayetteville, Gastonia, Greensboro, Greenville, Hickory, High Point, Monroe, New Bern, Raleigh, Rocky Mount, Statesville, Wilmington, and Winston-Salem.

distances (one-way) patients who reside in mobile PET counties would have to travel to find fixed PET sites:

- A patient from Salisbury in Rowan County would have to travel 43 miles to Charlotte or 39 miles to Winston-Salem.
- A patient from Thomasville in Davidson County would have to travel 20 miles to Winston-Salem or 69 miles to Charlotte.
- An Onslow County patient in Jacksonville would have to travel 37 miles to New Bern, 58 miles to Wilmington or 72 miles to Greenville to reach a fixed PET scanner.
- A patient from Laurinburg in Scotland County would travel 33 miles to Lumberton or 43 miles to Fayetteville.
- A patient from Elkin in Surry County would travel 44 miles to Winston-Salem or 37 miles to Statesville.
- A patient from Boone in Watauga County would likely drive 45 miles to Hickory.

To a healthy person, this may sound like a minor inconvenience but to a cancer patient, this amount of travel could be debilitating. The following chart highlights the projected number of new cancer cases by county for the mobile PET host sites. Although each case may not require a PET scan, this information does provide a quantitative measure of the number of residents with the potential need for PET services.

Mobile PET Host Sites – New Cancer Cases by County 2014

Host Site	County	No. of New Cancer Cases by County-2014
Albemarle Hospital	Pasquotank & Camden Counties	**292**
Caldwell Memorial	Caldwell	**542**
Grace Hospital	Burke	**595**
Valdese General Hospital	Burke	
Carteret General Hospital	Carteret	**543**
Cleveland Regional Medical Center	Cleveland	**621**
Novant Health Thomasville Medical Center	Davidson	**1,035**
Johnston Memorial Hospital	Johnston	**922**
Lenoir Memorial Hospital	Lenoir	**388**
MedWest Harris	Jackson	**259**
Northern Hospital of Surry County	Surry	**492**
Onslow Memorial Hospital	Onslow	**729**
Park Ridge Health	Henderson	**872**
Randolph Hospital	Randolph	**876**
Novant Health Rowan Medical Center	Rowan	**844**
Rutherford Regional Medical Center	Rutherford	**487**
Scotland Memorial Hospital	Scotland	**217**
Outer Banks Hospital	Dare	**255**
Watauga Medical Center	Watauga	**285**
Wayne Memorial Hospital	Wayne	**720**
Wilson Medical Center	Wilson	**508**
TOTAL NEW CANCER CASES FOR COUNTIES USING MOBILE PET SERVICES (WITH NO FIXED PET SITES)		**11,482**

Source: North Carolina State Center for Health Statistics, NC Cancer Projections 2000-2013. www.schs.state.nc.us/schs/data/cancer.cfm. Mobile PET host sites located in counties with fixed PET scanners were not included in this chart (ex. Duke Raleigh Hospital in Wake County and Lake Norman Regional in Iredell County were excluded due to availability of fixed PET services in county.)

Statement of alternatives to the proposed change that were considered and found not feasible

Out of County Travel to Access Fixed PET/CT Scanner

The viable options to address the lack of mobile PET capacity are extremely limited. Healthcare providers can continue to reluctantly ask patients to travel out of county to obtain this important diagnostic service at fixed PET sites. This alternative is not feasible for many reasons, including, but not limited to, the following:

1. Excessive travel time for patients suffering serious illnesses.
2. The loss of work/wages for spouses and/or caregivers to assist the patient.
3. The length of time required to travel and obtain a PET procedure at a fixed site.
4. The additional costs to the patient associated with out of county travel, which may include gas, food, lodging, etc.

Seek Additional Mobile PET Scanner Time from Existing Mobile PET Vendor

The option of requesting additional mobile PET time from the existing two mobile PET units may not be feasible since both existing PET units exceed a reasonable capacity threshold of 2600 scans annually and because each mobile already has a significant number of host sites that to which they have already, by contact, committed time. Based on the current service load for these mobile PET units, it would be difficult for existing PET sites or hospitals looking to add mobile PET services to obtain the mobile PET time necessary to develop a consistent program or grow its existing service.

Seek Approval of a New Fixed PET/CT Scanner

The alternative of applying for a fixed PET scanner is limited by the annual need determinations in the SMFP, which are based on six multi-county Health Service Areas (HSAs). Providers may not be allowed to apply for fixed PET scanners until a need determination is generated in the SMFP for a specific Health Service Area ("HSA"). During the past five years of SMFPs (2009-2013 SMFPs), the annual state health plans have only shown a need for one new fixed PET scanner, which is for Health Service Area II (the Triad) in the 2013 SMFP. A mobile PET scanner also differs from fixed PET scanners in that a single mobile PET scanner is capable of serving a larger portion of the State, which extends PET service to multiple host site locations in communities that are not reasonably proximate to fixed PET/CT scanners.

Need Method for 2 Mobile PET/CT scanners in Eastern & Western Mobile PET Service Areas

Novant Health and MedQuest also considered a change to the mobile PET need methodology for future State Medical Facilities Plan (using the 2014 SMFP as an example);

POSSIBLE REVISION for 2015 SMFP:
Table 9M(1): PET Scanner Provider of Mobile Dedicated Scanners

PET Scanners Planning Region	Provider Name	Procedures	Utilization Rate Year 2012-2013 Procedures/2600 as Capacity	Determination by Criteria - 80% of Present Capacity
1 (HSAs I, II, III)	Alliance Imaging	2,858	2,858/2,600 = 110%	1
2 (HSAs IV, V, VI)	Alliance Imaging	2,933	2,933/2,600 =113%	1
		5,791		

This alternative creates a methodology with need determinations for mobile PET scanners based on existing mobile PET/CT scanners exceeding a defined capacity threshold.
The suggested change for mobile PET scanners is consistent with the treatment of fixed PET scanners. If capacity is defined as 2,600 procedures annually, then a need determination would be generated when a single existing mobile PET scanner reaches 2,080 procedures (2,600 x .80 = 2,080 procedures). This is a standard health planning practice that is applied in some form or another to fixed PET services, MRI scanners (including fixed *and mobile*), lithotripters, cardiac catheterization equipment, acute care beds, operating rooms, and nursing facility beds.

One of the most significant disadvantages of this approach to establishing a mobile PET Need method in the 2015 SMFP is that it likely results in a net increase in the combined mobile and fixed PET/CT scanner inventory in North Carolina. Today, that inventory includes 27 fixed PET/CT scanners and 2 mobile PET/CT scanners, for a total of 29 PET/CT scanners. If this mobile PET scanner need method became part of Chapter 9 of the 2015 SMFP, in the future the result potentially would be 27 fixed PET/CT scanners and 4 mobile PET/CT scanners for a total inventory of 31 mobile and fixed PET/CT scanners in North Carolina. This mobile PET need method may have the unintended consequence of increasing the total fixed and mobile PET scanner inventory in North Carolina at a time when there are several under-utilized (fixed) PET/CT scanners in the inventory in NC.

2015 SMFP Policy to Create a Health Planning-Based Process to Increase the Number of Mobile PET Scanners by the Conversion of Existing Hospital-Owned Fixed PET/CT Scanners

This is the preferred approach to most effectively address both the pent-up demand for more mobile PET/CT scanner capacity and the re-deployment of under-utilized fixed PET/CT scanners to more productive and accessible uses. And this approach does not increase the overall inventory of fixed and mobile PET/CT scanners in North Carolina.

Novant Health and MedQuest recommend the following change related to mobile PET scanners in Chapter 9 of the 2015 SMFP:

- Establish a 2015 SMFP health-planning based policy that allows existing hospital providers who own and operate more than one CON-approved fixed PET/CT scanner, for a one year filing period during the 2015 SMFP plan year (1/1/2015-12/31/2015), to seek approval to convert one of their existing fixed PET/CT scanners to a mobile PET/CT scanner through the replacement equipment provision identified at N.C. Gen. Stat. §131E-176(22a).

- Replace the mobile East & West mobile PET/CT service areas defined in current SMFPs with a mobile PET service area that includes the entire state of North Carolina for the 2015 SMFP plan year and beyond to permit all mobile PET/CT scanners including the existing mobile PET provider and any subsequent providers to serve all of North Carolina. The creation of a process to expand mobile PET capacity in North Carolina is of primary importance to the petitioner. However, the petitioner also believes that the East/West mobile PET service area definitions have outlived their usefulness. Enhanced choice and competition will be created if hospitals seeking to add mobile PET services or expand their days of mobile PET service will more readily be able to obtain at least two competing

proposals when there is more than a single mobile PET vendor able to offer mobile services across all of North Carolina.

Using this approach to expand mobile PET/CT scanner capacity also ensures that the many of the host sites for the proposed additional mobile PET/CT scanners would be part of health systems that already have experience with a mobile PET/CT scanner programs on various hospital campuses. This prior mobile PET experience helps ensure that the additional mobile PET/CT scanners will be operated efficiently, effectively, safely and consistent with quality standards. Furthermore, the MedQuest division of Novant Health already has extensive experience operating mobile imaging programs throughout North Carolina.

Evidence that the proposed change would not result in unnecessary duplication of health resources in the area.

The establishment of a 2015 SMFP policy for additional mobile PET scanners based on the conversion of existing PET/CT scanners will not result in unnecessary duplication of health services in North Carolina. Clearly, there is a need for additional mobile PET capacity as indicated by the data presented in this Petition and the letters of support in **Attachment 2**. Furthermore, the recommended mobile PET/CT scanner method would not increase the combined total number of 29 mobile and fixed PET/CT scanners in North Carolina today. Rather the proposed conversion of existing fixed PET/CT scanners would allow for a conversion of potentially under-utilized fixed PET/CT scanners to a more productive use as mobile PET/CT scanners. The number of mobile PET sites (29 sites) served by the single mobile PET vendor, even without considering the unfulfilled requests for mobile PET time by NHTMC, NHHMC, NHMMC, and NHRMC, has surpassed the ability and capacity of the two existing mobile PET units. The existing mobile PET units are reaching the eight year mark[11] and undoubtedly will begin requiring more maintenance and downtime which could further impact the current availability of mobile PET services.

Evidence that the requested change is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access, and Value.

The request to implement a mobile PET methodology is consistent with the three Basic Principles governing the development of the State Medical Facilities Plan. In the 2014 SMFP, Chapter 1, the "Basic Principles Governing the Development of This Plan" are found at pages 2-4. These three basic principles are called: (1) Safety and Quality; (2) Access; and (3) Value.

Safety and Quality

The ability of healthcare providers to offer the best technology for patients improves the quality and effectiveness of care that patient receives. In addition, Novant Health and its affiliated radiology groups are experienced providers of both fixed and mobile PET/CT imaging services for their patients. Based on data in the 2014 SMFP, Table 9L, page 140, Novant Health Forsyth Medical Center in Winston-Salem operates the single busiest fixed PET/CT scanner in North Carolina (2,615

[11]According to Alliance, replacement exemptions were obtained in 2006.

annual PET/CT scans during FFY 2012)[12]and is in the process of developing a second fixed PET/CT scanner at NHFMC to support the very busy Cancer Center on the NHFMC campus. Novant Health Presbyterian Medical Center in Charlotte, also operates the 8th busiest single PET/CT scanner in North Carolina based on data in the 2014 SMFP and serves many cancer patients. Also, four Novant Health acute care hospitals serve as host sites for a mobile PET/CT scanner for 1 to 3 days per month per site. Thus, these sites have mobile pads in place and are experienced with assisting patients in getting scheduled for and accessing mobile PET imaging locally.

Access

Accessibility to services has always been an integral issue for health planning in North Carolina and a top priority for the SHCC. Fundamentally, most health care services are sought and consumed locally and based on the doctor patient relationship. Thus, the Novant Health acute care hospitals in Thomasville, Salisbury, Huntersville and Matthews are experienced with maximizing local access to mobile PET imaging within the constraints of the days when the Alliance Imaging mobile PET scanner is on site. Two of these Novant Health acute care hospitals have linear accelerators to provide radiation therapy treatments for cancer patients on their campuses (NHRMC and NHMMMC) and a third hospital (NHHMC) has recently received the state's approval to place a previously CON-approved linear accelerator on its campus. See **Attachment 3**. Thus, since cancer patients are still the primary users of PET imaging technology, the ability for Novant Health to add more days of mobile PET services at these hospitals, via the conversation of one of its fixed PET scanners to a mobile PET scanner, will expand local access to the imaging modality that goes hand in glove with the diagnosis and treatment of cancer patients.

The accessibility to mobile PET services for healthcare providers and their patients, particularly in smaller counties and towns, as well as rural areas, has reached a point that action must be taken by the SHCC in order to improve the availability of these services that providers and patients are demanding.

Value

The SHCC defines health care value as the maximum health care benefit per dollar expended. Healthcare value will be achieved by reducing costs to patients related to unnecessary out of county travel, improving the quality of care, increasing local accessibility to PET services for all North Carolina residents and local healthcare providers, and eliminating the need for other studies or procedures when a PET imaging study is the most effective modality, capturing both anatomic and metabolic information about each patient's tumors.

PET imaging is more complex than other common imaging modalities and therefore it is a more expensive service. Novant Health can purchase a mobile PET scanner under $2 million and drastically reduce annual operating expenses with the implementation of a mobile PET unit. The overall reduction of expenses allows a healthcare provider to reduce current charges which benefits

[12]SMFP Table 9L shows that during FFY 2012 CMC performed 3,036 PET/CT scans on 2 fixed PET/CT scanners or an average of 1,518 PET scans per scanner and Duke University Medical Center performed 4,474 PET/CT scans on 2 fixed PET/CT scanners or an average of 2,237 PET scans per scanner.

patients and third party payors. More significantly, the ability to enhance accessibility for the medically underserved in their local communities will greatly enhance the quality of life for cancer patients by bringing the state of the art technology to their communities.

In addition, if Novant Health[13] were able to convert one of its existing PET/CT scanners to a mobile PET/CT scanner to serve at least the existing four Novant Health hospital mobile PET scanner sites in Huntersville, Matthews, Thomasville, and Salisbury, this would free up Alliance Imaging's mobile PET scanners and allow AI to address unfulfilled requests for more mobile PET time at existing AI host sites or to accommodate requests from new potential AI mobile PET sites.

Conclusion

The petitioners, Novant Health, Inc. and MedQuest Associates, Inc., are requesting that the State Health Coordinating Council recognize the disparity in the treatment of mobile PET services in the State Medical Facilities Plan and request that the SHCC take action to adopt a Policy in the 2015 SMFP which would create a health-planning based process for the conversion of existing hospital fixed PET/CT scanners to mobile PET/CT scanners. This is approach most effectively addresses both the pent-up demand for more mobile PET/CT scanner capacity and the re-deployment of under-utilized fixed PET/CT scanners to more productive and accessible uses. This approach does not increase the overall inventory of fixed and mobile PET/CT scanners in North Carolina and is only in effect for a limited filing period.

The Status Quo cannot continue as current Alliance Imaging mobile PET scan data from the only two (2) existing mobile PET scanners in North Carolina continues to indicate that these two (2) mobile units are stretched beyond reasonable capacity. Without the intervention of the SHCC, this problem will only continue to place a strain on patients and healthcare providers by depriving patients and their physicians of beneficial local access to essential mobile PET services, where the primary consumers of PET imaging remain cancer patients.

File: Mobile PET Petition with SERVICE AREA 3-4-14.docx

[13]If the 2015 SMFP includes a process by which existing, CON-approved fixed PET/CT scanners can be converted to mobile PET/CT scanners, Novant Health anticipates, at this time, that the Novant Health PET/CT scanner for CON Project I.D. #G-6867-03 would be converted to a mobile PET/CT scanner. This fixed PET/CT scanner is currently operational at Novant Health Forsyth Medical Center in the radiology department.

Table of Attachments

Attachment #1: Alliance Imaging's January 2014 Registration & Inventory of Medical Equipment: Mobile PET Scanners: PET CT Unit 45 (West) and PET CT Unit 44 (East)

Attachment #2: Letters of Support from Novant Health Acute Care Hospitals with Current and Future Mobile PET/CT Scanner Host sites: NHTMC, NHRMC, NHMMC, NHHMC, and NHKMC

Attachment #3: Feb. 7, 2014 Declaratory Ruling Request Approving Development of Previously CON-Approved Linear Accelerator at NHHMC

Attachment #4: WHO (World Health Organization): Imminent global cancer 'disaster' reflects aging, lifestyle factors by Tim Hume & Jan Christensen, CNN (February 4, 2014); June 11, 2013 CMS Decision Memorandum for Positron Emission Tomography (FDG) for Solid Tumors (*CMS agrees to cover three follow-up FDG PET scans rather than just one); Variations in Use of PET among Medicare Beneficiaries with Non-Small Cell Lung Cancer, 1998-2007.* Michaela Dinan, PhD, Lesley H. Curtis, PhD, William R. Carpenter, PhD, et al.

Attachment #1

1/22/14 data check. PDL

Registration and Inventory of Medical Equipment
Mobile Positron Emission Tomography Scanners
January 2014 **PET CT Unit 45** – WEST – 18 Host Sites

Instructions
This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile positron emission tomography scanners. Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 31, 2014.**

1. Complete and sign the form
2. Return the form by one of two methods:
   a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
   b. Mail the form to Kelli Fisk, Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

   Alliance Healthcare Services
   (Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

   100 Bayview Circle, Suite 400
   (Street and Number)

   Newport Beach CA 92660 (City) (State) (Zip) **(800) 544-3215** (Phone Number)

3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

   Freda Crawford (Name) **Manager Operations** (Title)

   1233 Front Street Suite A Raleigh, NC 27612
   (Street and Number) (City) (State) (Zip)

   336 207 5613 (Phone Number) **fcrawford@allianceimaging.com** (Email)

4. Information Compiled or Prepared by: **David French** (Name)

   (336) 349-6250 (Phone Number) **djfrench45@bellsouth.net** (Email)

RECEIVED
JAN 22 2014
DHHS – DHSR
MEDICAL FACILITIES PLANNING BRANCH

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 1	Service Site Number 2
Service Site Information: Please include **all** of the information requested for each location.	Presbyterian Hospital Matthews 1500 Matthews Township Parkway Matthews, NC 28105 Mecklenburg	Cleveland Regional Medical Cent 201 East Grover St Shelby, NC 28150 Cleveland
Procedures* – Inpatient	3	20
Procedures* – Outpatient	131	481
Total # of procedures* for report period	134 ✓ (132 Hospital LRA 2014)	501 ✓ (494 Hospital LRA 2014)
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	134 hrs 10/01/2012 – 9/30/2013	501 hr 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	134 hrs	501 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

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Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 3	Service Site Number 4
Service Site Information: Please include **all** of the information requested for each location.	The Presbyterian Hospital 10030 Gilead Road Huntersville, NC 28078 Mecklenburg	Lake Norman Medical Center 171 Fairview Road Mooresville, NC 28117 Mecklenburg
Procedures* – Inpatient	4	2
Procedures* – Outpatient	193	196
Total # of procedures* for report period	197 ✓ (201 Hospital LRA 2014)	198 ✓ (171 Hospital LRA 2014)
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	197 hrs 10/01/2012 – 9/30/2013	198 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	197 hrs	198 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 5	Service Site Number 6
Service Site Information: Please include **all** of the information requested for each location.	Margaret R. Pardee Memorial Hosp 800 North Justice St Hendersonville, NC 28791 Henderson	Northern Hosp of Surry County 830 Rockford Street Mount Airy, NC 27030 Surry
Procedures* – Inpatient	1	0
Procedures* – Outpatient	165	87
Total # of procedures* for report period	166 ✓ (160 Hospital LRA 2014)	87 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	166 hrs	87 hrs
	10/01/2012 – 9/30/2013	10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	166 hrs	87 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 7	Service Site Number 8
Service Site Information: Please include **all** of the information requested for each location.	Park Ridge Hospital 100 Hospital Drive Fletcher, NC 28732 Henderson	Rowan Regional Medical Center 514 Corporate Circle Salisbury, NC 28147 Rowan
Procedures* – Inpatient Procedures* – Outpatient Total # of procedures* for report period	**0** **126** **126** ✓	**0** **216** **216** ✓ (223 Hospital IRA 2014)
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	126 hrs 10/01/2012 – 9/30/2013	216 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	126 hrs	216 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

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Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 9	Service Site Number 10
Service Site Information: Please include **all** of the information requested for each location.	Rutherford Hosp., Inc. 288 South Ridgecrest Ave. Rutherfordton, NC 28193 Rutherford	Watauga Medical Center 336 Deerfield Road Boone, NC 28607 Watauga
Procedures* – Inpatient	1	1
Procedures* – Outpatient	126	95
Total # of procedures* for report period	127 ✓	96 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	127 hrs 10/01/2012 – 9/30/2013	96 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	127 hrs	96 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number **11**	Service Site Number **12**
Service Site Information: Please include **all** of the information requested for each location.	WestCare Health System 68 Hospital Drive Sylva, NC 28779 Jackson	Stanly Regional Medical Center 301 Yadkin Street Albemarle, NC 28001 Stanly
Procedures* – Inpatient	**0**	**0**
Procedures* – Outpatient	**292**	**144**
Total # of procedures* for report period	**292** ✓	**144** ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	292 hrs 10/01/2012 – 9/30/2013	144 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	292 hrs	144 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 13	Service Site Number 14
Service Site Information: Please include **all** of the information requested for each location.	Blue Ridge-Grace Hospital ✓ 2201 S. Sterling Street Morganton, NC 28655 Burke	Blue Ridge-Valdese Hospital 720 Malcolm Blvd Rutherford College, NC 28671 Burke
Procedures* – Inpatient	0	0
Procedures* – Outpatient	113	119
Total # of procedures* for report period	113 ✓	119 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	113 hrs 10/01/2012 – 9/30/2013	119 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	113 hrs	119 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number **15**	Service Site Number **16**
Service Site Information: Please include **all** of the information requested for each location.	Caldwell Memorial Hospital 321 Mulberry Street, SW Lenoir, NC 28645 Caldwell	Community General Health Partner 207 Old Lexington Rd Thomasville, NC 27360 Davidson
Procedures* – Inpatient	2	4
Procedures* – Outpatient	137	93
Total # of procedures* for report period	139 ✓	97 ✓ (98 Hospital LRA 2014)
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	139 hrs 10/01/2012 – 9/30/2013	97 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	139 hrs	97 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

Scan volumes for this time period include 19 scans performed using a temporary replacement unit for PET CT 45.

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8276H022244 PET CT Unit 45	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 17	Service Site Number 18
Service Site Information: Please include **all** of the information requested for each location.	Randolph Hospital 364 White Oak Street Asheboro, NC 27203 Randolph	Cone Health – FISEDetc 2630 Willard Dairy Rd. High Point, NC 27265 Guilford
Procedures* – Inpatient Procedures* – Outpatient Total # of procedures* for report period	**0** **120** **120** ✓	**0** **61** **61** ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	120 hrs 10/01/2012 – 9/30/2013	61 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	120 hrs	61 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 3: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received PET scanner services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be the same as the total number of procedures reported on page 2 of this form.

Service Site Name: **No patient origin data is collected by Alliance**

County in which service was provided: **Not applicable**

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	
35. Franklin		71. Pender			
36. Gaston		72. Perquimans		**Total Number of Patients**	**2933**

Name of entity that acquired the equipment (from page 1) **Alliance Healthcare Services**

Section 4: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature Freda J Crawford

Print Name **Freda Crawford**

Date signed **January 22, 2014**

Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 31, 2014.** .

1. Complete and sign the form
2. Return the form by one of two methods:
   a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
   b. Mail the form to Kelli Fisk in the Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

1/22/14 data checked PB

Registration and Inventory of Medical Equipment
Mobile Positron Emission Tomography Scanners
January 2014 **PET CT Unit 44** – East (11 Host Site)

Instructions
This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile positron emission tomography scanners. Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 31, 2014.**

1. Complete and sign the form
2. Return the form by one of two methods:
   a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
   b. Mail the form to Kelli Fisk, Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

   Alliance Healthcare Services
   (Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

   100 Bayview Circle, Suite 400
   (Street and Number)

   Newport Beach CA 92660 (City) (State) (Zip) **(800) 544-3215** (Phone Number)

3. Chief Executive Officer or approved designee who is certifying the information in this registration form:

   Melissa VanOostrom (Name) **Manager Operations** (Title)

   1233 Front Street Suite A Raleigh, NC 27612
   (Street and Number) (City) (State) (Zip)

   910-340-1494 (Phone Number) **mvanoostrom@allianceimaging.com** (Email)

   RECEIVED
   JAN 22 2014
   DHHS – DHSR
   MEDICAL FACILITIES PLANNING BRANCH

4. Information Compiled or Prepared by: **David French**
   (Name)

   (336) 349-6250 (Phone Number) **djfrench45@bellsouth.net** (Email)

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8256H022243 PET CT Unit 44	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 1	Service Site Number 2
Service Site Information: Please include **all** of the information requested for each location.	Albermarle Hospital 1144 North Road Street Elizabeth City, NC 27909 Pasquotank	Duke Raleigh Hospital 3400 Executive Drive Raleigh, NC 27609 Wake
Procedures* – Inpatient	1	0
Procedures* – Outpatient	238	545
Total # of procedures* for report period	239 ✓ (243 Hospital LRA 2014)	545 ✓ (525 Hospital LRA 2014)
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	239 hrs 10/01/2012 – 9/30/2013	545 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	239 hrs	545 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8256H022243 PET CT Unit 44	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 3	Service Site Number 4
Service Site Information: Please include **all** of the information requested for each location.	Johnston Memorial Hospital Auth 509 N. Bright Leaf Blvd. Smithfield, NC 27577 Johnston	Lenoir Memorial Hospital 100 Airport Road Kinston, NC 28501 Lenoir
Procedures* – Inpatient	0	2
Procedures* – Outpatient	197	168
Total # of procedures* for report period	197 ✓ (198 Hospital LRA 2014)	170 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	197 hrs	170 hrs
	10/01/2012 – 9/30/2013	10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	197 hrs	170 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8256H022243 PET CT Unit 44	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 5	Service Site Number 6
Service Site Information: Please include **all** of the information requested for each location.	Outer Banks Hospital 4800 S. Croatan Highway Nags Head, NC 27959 Dare	Scotland Memorial Hospital, Inc 500 Lauchwood Drive Laurinburg, NC 28352 Scotland
Procedures* – Inpatient	0	0
Procedures* – Outpatient	114	149
Total # of procedures* for report period	114 ✓	149 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	114 hrs 10/01/2012 – 9/30/2013	149 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	129 hrs	149 hrs

* PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8256H022243 PET CT Unit 44	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 7	Service Site Number 8
Service Site Information: Please include **all** of the information requested for each location.	Southeastern Regional Medical 300 West 27th St. Lumberton, NC 28358 Robeson	Wayne Memorial Hospital 2700 Wayne Memorial Dr. Goldsboro, NC 27534 Wayne
Procedures* – Inpatient	0	0
Procedures* – Outpatient	257	332
Total # of procedures* for report period	257 ✓	332 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	257 hrs 10/01/2012 – 9/30/2013	332 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	257 hrs	332 hrs

* PET scan means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Name of entity that acquired the equipment (from page 1) Alliance Healthcare Services

Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 ☐ Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8256H022243 PET CT Unit 44	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number 9	Service Site Number 10
Service Site Information: Please include **all** of the information requested for each location.	Wilson Medical Center 1705 South Tarboro St. Wilson, NC 27893 Wilson	Carteret General Hospital 3402 Arendell St. Morehead City, NC 28557 Carteret
Procedures* – Inpatient	38	1
Procedures* – Outpatient	351	225
Total # of procedures* for report period	389 ✓	226 ✓
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	339 hrs 10/01/2011 – 9/30/2012	226 hrs 10/01/2012 – 9/30/2013
Total number of hours in operation by site for report period.	389 hrs	226 hrs

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Section 2: Equipment and Procedures Information

Time Period for Report: ☒10/01/2012 – 9/30/2013 . ☐ Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Information (one scanner per page)	
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	1M9A6A8256H022243 PET CT Unit 44	
Date of purchase	2006 (Replacement Exemption Obtained)	
Purchase price	$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number **11**	Service Site Number __
Service Site Information: Please include **all** of the information requested for each location.	Onslow Memorial Hospital 317 Western Blvd Jacksonville, NC 28546 Onslow	
Procedures* – Inpatient Procedures* – Outpatient Total # of procedures* for report period	**2** **238** **240** ✓	
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	240 hrs 10/01/2012 – 9/30/2013	
Total number of hours in operation by site for report period.	240 hrs	

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

Section 3: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received PET scanner services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be the same as the total number of procedures reported on page 2 of this form.

Service Site Name: **No patient origin data is collected by Alliance**

County in which service was provided: **Not applicable**

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	
35. Franklin		71. Pender			
36. Gaston		72. Perquimans		**Total Number of Patients**	**2858**

Name of entity that acquired the equipment (from page 1) **Alliance Healthcare Services**

Section 4: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature *Melissa VanOostrom*

Print Name **Melissa VanOostrom**

Date signed **January 22, 2014**

Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 31, 2014.**

1. Complete and sign the form
2. Return the form by one of two methods:
   a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
   b. Mail the form to Kelli Fisk in the Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Attachment #2

February 28, 2014

NOVANT HEALTH
Huntersville Medical Center
10030 Gilead Road
Huntersville, NC 28078
novanthealth.org

Mr. Jerry Parks, Chairman
State Health Coordinating Council
Division of Health Service Regulation
Medical Facilities Planning Branch
809 Ruggles Drive Raleigh, NC 27603

RE: Letter of Support for Novant Health and MedQuest's Petition to Amend the 2015 State Medical Facilities Plan to Permit the Conversion of Existing Hospital Fixed PET/CT Scanners to Mobile PET/CT Scanners

Dear Chairman Parks:

I am the President of Novant Health Huntersville Medical Center ("NHHMC") in Huntersville, NC (Mecklenburg County). Novant Health Huntersville Medical Center is a full-service, 75-bed community hospital with an emergency department, medical and surgical services, and radiology, lab, and pharmacy services. In addition, NHHMC's Cancer Center is accredited by the Commission on Cancer as an Integrated Cancer Program. NHHMC was recently approved to add a previously CON-approved linear accelerator on the NHHMC campus. In addition, NHHMC and its medical staff also offers the following services on the NHHMC campus today: chemotherapy and other infusion therapies, surgical oncology, hematology/oncology, nurse navigators, tailored rehabilitation programs for cancer patients, advanced diagnostic imaging, a comprehensive breast center with screening mammograms, biopsies, ultrasound, and needle localizations, a second opinion clinic, inpatient oncology, and an interdisciplinary team approach and weekly collaboration to evaluate and discuss the best treatment options for each patient. The NHHMC Cancer Center has helped community residents beat cancer and lead full, happy lives. NHHMC's patients benefit from a customized approach to cancer care. The cancer care physician specialists on the NHHMC medical staff include Radiation Oncologists with Southeast Radiation Oncology Group, P.A.; medical oncologists and hematology/oncologists at Lake Norman Hematology Oncology; and a medical oncologist at Southern Oncology Specialists.

NHHMC has contracted with Alliance Imaging to host a mobile PET/CT scanner on its campus. Currently, Alliance Imaging is only able to offer mobile PET/CT scan services at NHHMC one Monday per month for a full day defined as 7am - 10pm and every other Thursday for a half day defined as 2:30 – 8:00pm. This equates to 26 hours per month of local mobile PET/CT scanner service. During FFY 2013, about 200 mobile PET/CT scans were performed at NHHMC. The mobile PET/CT scanner is used to support the care of cancer patients provided at NHHMC and the cancer specialists mentioned above. However, since the mobile PET/CT scanner is only available locally for the equivalent of 2 days per month, many of our cancer patients find they must travel to downtown Charlotte to get a needed PET/CT scan in the timely manner. These patients are often fragile and very sick and the strain of travelling away from home to get a needed PET/CT scan or delaying treatment creates an unnecessary burden for patients and their families.

I encourage the State Health Coordinating Council to approve the petition submitted by Novant Health and MedQuest to allow the expansion of mobile PET capacity. The lack of accessibility to mobile PET imaging services has a real impact on our cancer patients and this matter requires immediate attention.

Sincerely,

Tanya S. Blackmon

Tanya Blackmon, President
Novant Health Huntersville Medical Center

File: MobilePETHvilleMedCenterSuppLtr2014.docx

NOVANT HEALTH

Matthews Medical Center
1500 Matthews Township Parkway
Matthews, NC 28105

March 3, 2014

Mr. Jerry Parks, Chairman
State Health Coordinating Council
Division of Health Service Regulation
Medical Facilities Planning Branch
809 Ruggles Drive Raleigh, NC 27603

RE: Letter of Support for Novant Health and MedQuest's Petition to Amend the 2015 State Medical Facilities Plan to Permit the Conversion of Existing Hospital Fixed PET/CT Scanners to Mobile PET/CT Scanners

Dear Chairman Parks:

I am the President of Novant Health Matthews Medical Center ("NHMMC") in Matthews, North Carolina (Mecklenburg County). NHMMC is a full-service community hospital offering 24 X 7 emergency department services, medical and surgical services, Hospice & Palliative Care, GI Endoscopy, Cardiac Catheterization Lab, Sleep Medicine, Pharmacy, Laboratory services and Imaging including mobile PET/CT scanner imaging. NHHMC is licensed for 137 beds comprised of a 9-bed ICU, 8 Level III Neonatal beds, 126 medical/surgical acute inpatient beds, including LDRP beds, and 3 hospice inpatient beds. Also, located on the campus of NHHMC in a freestanding outpatient building is a radiation therapy treatment center with one linear accelerator, which is owned and operated by a group of radiation oncologists called Southeastern Radiation Oncology Group, P.A. ("SERO"). This SERO linear accelerator is one of the single business linear accelerators in North Carolina and data in the 2014 State Medical Facilities Plan shows that the single linear accelerator at SERO's Matthews Radiation Oncology Center performed 9,489 ESTV-weighted annual radiation therapy treatments in FFY 2012. SERO radiation oncologists, Matthews Hematology Oncology Associates (medical oncologists & a hematologist/oncologist) are on the active medical staff at NHMMC and provide care for our cancer patients, along with cancer surgeons, pulmonologists, gastroenterologists, other medical specialists, radiologists, and pathologists.

NHMMC has contracted with Alliance Imaging to host a mobile PET/CT scanner on its campus. Currently, Alliance Imaging is only able to offer mobile PET/CT scan services at NHMMC one Monday per month for a half-day defined as 2:30 -8:00 pm and every other Thursday for a half-day defined as 2:30 -8:00 pm. This is the equivalent of 1.5 days or 16 hours per month for local access to mobile PET/CT imaging in Matthews. The mobile PET/CT scanner is used to support the care of cancer patients provided by NHMMC and the cancer specialists mentioned above. However, since the mobile PET/CT scanner is only available locally for the equivalent of 21.5 days each month, many of our cancer patients find they must travel to downtown Charlotte to get a needed PET/CT scan in the timely

manner. These patients are often fragile and very sick and the strain of travelling away from home to get a needed PET/CT scan or delaying treatment creates an unnecessary burden for patients and their families.

I encourage the State Health Coordinating Council to approve the petition submitted by Novant Health and MedQuest to allow the expansion of mobile PET/CT scanner capacity. The lack of accessibility to mobile PET/CT imaging services has a real impact on our cancer patients and this matter requires immediate attention.

Sincerely,

Roland Bibeau, President
Novant Health Matthews Medical Center

File: MobilePETMatthewsMedCenterSuppLtr2014.docx

NOVANT HEALTH

Rowan Medical Center

612 Mocksville Avenue
Salisbury, NC 28144

T 704-210-5000

February 27, 2013

Mr. Jerry Parks, Chairman
State Health Coordinating Council
Division of Health Service Regulation
Medical Facilities Planning Branch
809 Ruggles Drive Raleigh, NC 27603

RE: Letter of Support for Novant Health and MedQuest's Petition to Amend the 2015 State Medical Facilities Plan to Permit the Conversion of Existing Hospital Fixed PET/CT Scanners to Mobile PET/CT Scanners

Dear Chairman Parks:

I am the President of Novant Health Rowan Medical Center ("NHRMC") in Salisbury, North Carolina. Our hospital is a full-service community hospital offering medical and surgical services, behavioral health and rehabilitation beds, lab, pharmacy, radiology, an emergency department, sleep medicine, stroke services, orthopedics, diabetes & nutrition services. In collaboration with cancer specialists in our community, NHRMC and these physicians also offer local cancer services including breast health, imaged-guided tumor biopsies, chemotherapy, biologic therapies, genetic counseling for patients with a strong family history of cancer, CT simulation for radiation treatment planning, radiation therapy services by a linear accelerator, and hospice services. During FFY 2013 NHRRMC performed over 7,600 linear accelerator procedures for 246 patients. Currently, three hematologist/oncologists practicing at Carolina Oncology Associates in Salisbury are on the NHRMC medical staff. Dr. Gregory Mitro of Southeastern Radiation Oncology Group, P.A., serves as the Medical Director for Radiation Oncology at NHRMC.

NHRMC has contracted with Alliance Imaging for many years to host a mobile PET/CT scanner on its campus to support the cancer program. Currently, Alliance Imaging is only able to offer NHRRMC on site mobile imaging services one Monday per month for 15 hours (7:00 am- 10:00 pm) every other Thursday for 5.5 hours (2:30 – 8:00pm). Thus, NHRRMC can offer its cancer patients local access to PET/CT scan imaging, an important diagnostic tool in cancer diagnosis and treatment, for only 26 hours per month. I am told that since 2003-2004, there have been only two mobile PET scanners owned by Alliance Imaging that are CON-approved to operate North Carolina.

I speak for our hospital and our cancer specialist physician partners when I say, our cancer patients are in need of timely and convenient access to PET imaging services. Over the last several years, delays in the provision of care due to the unavailability of the mobile PET service (such as contracted mobile PET on site at the local hospital only 1 full day and 2 half days per month) are not acceptable when the State has the ability to authorize additional mobile PET capacity. Our cancer patients are fragile and very ill such that the inconvenience and strain of travelling to other facilities for healthcare or delaying treatment creates an unnecessary burden for them.

I urge the State Health Coordinating Council to approve the petition submitted by Novant Health and MedQuest to allow the expansion of mobile PET capacity. The lack of accessibility to mobile PET imaging services has a real impact on our cancer patients and this matter requires immediate attention.

Sincerely,

Dari Caldwell

Dari Caldwell, R.N., PhD, President
Novant Health Rowan Medical Center

NOVANT HEALTH

March 3, 2014

Thomasville Medical Center
207 Old Lexington Road
Thomasville, NC 27360

T 336-476-2526
novanthealth.org

Mr. Jerry Parks, Chairman
State Health Coordinating Council
Division of Health Service Regulation
Medical Facilities Planning Branch
809 Ruggles Drive Raleigh, NC 27603

RE: Letter of Support for Novant Health and MedQuest's Petition to Amend the 2015 State Medical Facilities Plan to Permit the Conversion of Existing Hospital Fixed PET/CT Scanners to Mobile PET/CT Scanners

Dear Chairman Parks:

I am the President of Novant Health Thomasville Medical Center ("NHTMC") located in Thomasville, NC (Davidson County). Our hospital is a full-service community hospital offering emergency department care, medical and surgical inpatient services, geriatric behavioral health, cardiac and stroke care, breast health, occupational medicine, wound care, women's services including a Women's Heart Center, respiratory therapy, lab, pharmacy, and imaging, including mobile PET/CT scanner services. NHTMC has Centers of Excellence and Specialty programs in: heartburn treatment, geriatric behavioral health, total joint replacement, a chest pain center, and a sleep disorders center.

Novant Health Oncology Specialists, a group of hematologist/oncologists, medical oncologists, and gyn oncologists has its main office in Winston-Salem proximate to the Novant Health Forsyth Medical Center Cancer Center and has many satellite offices throughout the greater Triad Region including Statesville (Iredell County), Wilkesboro (Wilkes County), Mt. Airy (Surry County), Mocksville (Davie County), and Thomasville/Lexington (Davidson County). The NHOS office located between Thomasville and Lexington offers on-site chemotherapy, and medical and gynecological oncology services.

NHTMC has contracted with Alliance Imaging to host a mobile PET/CT scanner on its campus. Currently, Alliance Imaging is only able to offer mobile PET/CT scan services at NHTMC every other Tuesday for a half-day defined as 2:30-8:00pm or about 11 hours per month. The mobile PET/CT scanner is used to support the care of cancer patients seen at NHOS. However, since the mobile PET/CT scanner is only available locally for two or three half days per month, many Davidson County residents who are cancer patients find they must travel out of county (Winston-Salem, High Point, Charlotte) for a necessary PET/CT scan. These patients are often debilitated and very sick and the strain of travelling away from home to get a needed PET/CT scan or delaying treatment creates an unnecessary burden for patients and their families.

I encourage the State Health Coordinating Council to approve the petition submitted by Novant Health and MedQuest to allow the expansion of mobile PET capacity. The lack of accessibility to mobile PET imaging services has a real impact on our cancer patients and this matter requires immediate attention.

Sincerely,

Kathie Johnson

Kathie A. Johnson, President
Novant Health Thomasville Medical Center

NOVANT HEALTH

Kernersville Medical Center

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Kernersville, NC 27284

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novanthealth.org

March 1, 2013

Mr. Jerry Parks, Chairman
State Health Coordinating Council
Division of Health Service Regulation
Medical Facilities Planning Branch
809 Ruggles Drive Raleigh, NC 27603

RE: Letter of Support for Novant Health and MedQuest's Petition to Amend the 2015 State Medical Facilities Plan to Permit the Conversion of Existing Hospital Fixed PET/CT Scanners to Mobile PET/CT Scanners

Dear Chairman Parks:

I am the President of Novant Health Kernersville Medical Center ("NHKMC") located in western Forsyth County. NHKMC opened in March 2011 and is a full service community hospital offering medical and surgical services (general, ENT, urology, ophthalmology, bariatrics, and orthopaedic) emergency department, pharmacy, radiology, lab, and diagnostic cardiac, neurological and gastrointestinal care. In addition, in June 2013 in a new medical office building on the campus of NHKMC we began assembling the components of a satellite cancer center including cancer specialty physicians and technology. The Kernersville medical office building includes offices for the same, radiation oncologists (Piedmont Radiation Oncology), cancer surgeons (Novant Health Salem Surgical Associates), hematologist/oncologists and gyn oncologists (Novant Health Oncology Specialists) that practice at the Cancer Center at Forsyth Medical Center in Winston-Salem. The NHOS physicians have had a satellite office in Kernersville for about 20 years and the NHOS satellite office include chemotherapy services, as well. The NHOS, PRO, and NHSSA physicians and surgeons have been working together for many years to care for cancer patients in a coordinated and interdisciplinary manner. In addition, NHKMC was approved to relocate a linear accelerator to the NHKMC and place it in the medical office building. That linear accelerator began treating patients in late September 2013. The NHKMC satellite cancer program also offers other supportive services for cancer patients including Cancer Nurse Navigators and nutritionists.

The only component missing from our cancer satellite program is local access to PET/CT scan imaging which is standard of care for diagnosing, staging and re-staging, and monitoring tumor response to treatment. I am told that since 2003-2004, there have been only two mobile PET scanners owned by Alliance Imaging that are CON-approved to operate North Carolina. Since Alliance Imaging already serves 18 mobile PET/CT host sites in western North Carolina, it is unlikely they could accommodate a request from NHKMC for mobile PET service in the near term. I speak for our hospital and our cancer specialist physician partners when I say, our cancer patients are in need of timely, local access to PET imaging services. Our cancer patients are fragile and very ill such that the inconvenience and strain of travelling to other facilities PET/CT scans creates an unnecessary burden for them and their families.

I urge the State Health Coordinating Council to approve the petition submitted by Novant Health and MedQuest to allow the expansion of mobile PET capacity. The lack of accessibility to mobile PET imaging services has a real impact on our cancer patients and this matter requires immediate attention.

Sincerely,

Joanne Allen

Joanne Allen, President
Novant Health Kernersville Medical Center

File: MobilePETKvilleMedCenterSuppLtr2014.docx

Attachment #3

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

February 7, 2014

FACSIMILE & CERTIFIED MAIL

Denise M. Gunter, Esq.
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, North Carolina 27103

RE: Declaratory Ruling for Novant Health Presbyterian Medical Center
Project I.D. No. F-7518-06

Dear Ms. Gunter:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:CO:peb

cc: Lee M. Whitman, Esq., Wyrick Robbins Yates & Ponton, LLP, courtesy copy
Cheryl Ouimet, Chief Operating Officer, DHSR
Martha Frisone, Chief, Certificate of Need Section
Steven Lewis, Chief, Construction Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
Nadine Pfeiffer, Branch Manager, Medical Facilities Planning Section
June Ferrell, Special Deputy Attorney General, DOJ

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY RULING BY NOVANT HEALTH PRESBYTERIAN MEDICAL CENTER Project ID No. F-7518-06	))))	**DECLARATORY RULING**

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Novant Health Presbyterian Medical Center ("Presbyterian") has requested a declaratory ruling for authorization of a change in location of a linear accelerator from Novant Health Matthews Medical Center ("Matthews Site") to Novant Health Huntersville Medical Center ("Huntersville Site") for Project I.D. No. F-7518-06 on the grounds that the change does not constitute a material change in scope or physical location or a failure to materially comply with the representations made by Presbyterian in its Certificate of Need ("CON") application for its project. N.C.G.S. §§ 131E-181(a). This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Denise M. Gunter of Nelson Mullins Riley & Scarborough LLP has requested this ruling on behalf of Presbyterian and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

The 2006 State Medical Facilities Plan ("SMFP") contained a need determination for one additional linear accelerator in Service Area 7 (Mecklenburg, Anson, and Union counties). As a result of the need determination, Presbyterian filed a CON application, Project I.D. No. F-7518-06, on March 15, 2006. Presbyterian's application proposed to replace a refurbished linear accelerator to be installed in a medical office building in the Ballantyne area of southern Mecklenburg County. At the time, three other applicants (CMC-Union, Pineville Radiation Therapy, LLC and Radiation Oncology Centers of the Carolinas, Inc.) also filed CON applications pursuant to the 2006 SMFP linear accelerator need determination.

The CON Section approved the CMC-Union application, Project I.D. #F-7525-06, and disproved the other applicants. Presbyterian and Pineville Radiation Therapy Center, LLC appealed the CON Section's decision. The parties were able to reach a settlement in mediation. The settlement allowed Presbyterian to develop their proposed project, contingent upon their ability to demonstrate that Presbyterian installed and operated the refurbished linear accelerator for less than $750,000. Presbyterian was able to successfully demonstrate to the Department that it installed and operated the refurbished linear accelerator for that amount. Therefore, the Agency issued Presbyterian a CON (Project I.D. No. F-7518-06) to replace the refurbished linear accelerator with a new linear accelerator and relocate the replacement linear accelerator to Ballantyne.

In 2009, the Department issued a declaratory ruling to Presbyterian allowing it to relocate the replacement linear accelerator from Ballantyne to the Matthews Site. Presbyterian stated that in the 2009 declaratory ruling request that the linear accelerator was needed in Matthews to assist in handling the high number of radiation therapy cases being handled by the Southeastern

Radiation Oncology Group, P.A. (SERO) linear accelerator located on the Matthews campus. However, linear accelerator growth at the Mathews Site was not substantiated. Linear accelerator volumes reported in the draft 2014 SMFP are significantly lower than the volumes reported in the 2009 SMFP.

On October 23, 2013, the Department submitted a notice of intent to consider withdrawal of a CON to Presbyterian for Project I.D. No. F-7518-06 because the project was significantly behind schedule and little to known progress had been made. Presbyterian responded to the Department's letter by submitting a comprehensive progress report (CPR) on December 16, 2013. Simultaneously, Presbyterian submitted this request for declaratory ruling. In the CPR, Presbyterian summarized the project, provided justification for delays and changes in the project and referenced this proposed declaratory ruling request to change sites as demonstration of their intent to move forward to complete the project. Presbyterian stated in the CPR, that offering of services for the linear accelerator will be March 31, 2015. Presbyterian stated in the CPR that the linear accelerator can be developed most effectively at the Huntersville Site located at 10030 Gilead Road, Huntersville, North Carolina 28072.

ANALYSIS

The CON law would require a full review of Presbyterian's proposal if that change were to represent a material change in the physical location or scope of the project. N.C.G.S. § 131E-181(a). The requested linear accelerator relocation does not constitute a material change in the physical location or the scope of the proposed project for the following reasons:

At the time Presbyterian proposed to locate the linear accelerator at the Matthews Site, radiation volumes on the single linear accelerator at Matthews Radiation Oncology were growing significantly. However, the growth was not sustained. There is no linear accelerator anywhere in

the Town of Huntersville or in the neighboring northern Mecklenburg towns of Cornelius and Davidson, forcing cancer patients who are being treated by Novant Health physicians to travel to Presbyterian for their radiation therapy treatments. Relocating the Presbyterian linear accelerator to the Huntersville Site would enhance the services already offered by Huntersville's growing cancer program, and meet the needs of the growing cancer patient population in that area. The population around the Matthews Site, which was approved in the 2009 declaratory ruling, is significantly smaller than that at the Huntersville Site, and the existing linear accelerator in Matthews has experienced volume decreases. Presbyterian will not incur any additional cost to develop the linear accelerator at the Huntersville Site. There will be no increases in costs or charges to the public as a result of the declaratory ruling request. There is no ownership change proposed. The only change being proposed is a location change. The Ballantyne area, the Matthews Site, and the Huntersville Site are all in Mecklenburg County therefore the linear accelerator will remain in linear accelerator Service Area 7 (Mecklenburg, Anson, and Union counties). The linear accelerator can be developed and operated at the Huntersville Site in substantial material compliance with all aspects of Presbyterian's application including any applicable settlement materials.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw Presbyterian's CON if Presbyterian fails to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. Presbyterian will not be developing its project in a manner that is materially different from the representations made in its application, nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its CON.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that Presbyterian's proposal to change sites for the replacement and relocation of a linear accelerator from 1500 Matthews Township Parkway in Matthews to 10030 Gilead Road in Huntersville does not constitute a material change in the physical location or scope of the project, does not violate N.C.G.S. § 131E-181, and does not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b).

The Certificate of Need Section has extended the timetable for the project documented in the Department's acknowledgement of receipt of progress report letter dated December 20, 2013. The approved timetable for the project is as follows:

Milestone	Completion Date
Schematic Design Review & Sign-off Design Development	March 17, 2014
Design Development Review & Sign-off Construction Documents	April 21, 2014
Construction Documents Submitted to Construction, DHSR	June 9, 2014
Contract award	July 7, 2014
Ordering of medical equipment	September 8, 2014
25% completion of construction	September 8, 2014
50% completion of construction	November 10, 2014
75% completion of construction	January 12, 2015
Completion of construction	March 16, 2015
Offering services	March 31, 2015

Presbyterian will be held to the March 31, 2015 offering of services date and Huntsville Site location with no exceptions for additional timetable extensions or site relocations. The Department does not intend to approve any additional changes to the timetable or location of the project.

This the 7th day of February, 2014.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONERS by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Denise M. Gunter
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, North Carolina 27103

Courtesy Copy:

Lee M. Whitman
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607

This the 7th day of February, 2014.

Cheryl Ouimet
Chief Operating Officer

Attachment #4

WHO: Imminent global cancer 'disaster' reflects aging, lifestyle factors

By Tim Hume and Jen Christensen, CNN
updated 7:20 PM EST, Tue February 4, 2014

CNN.com

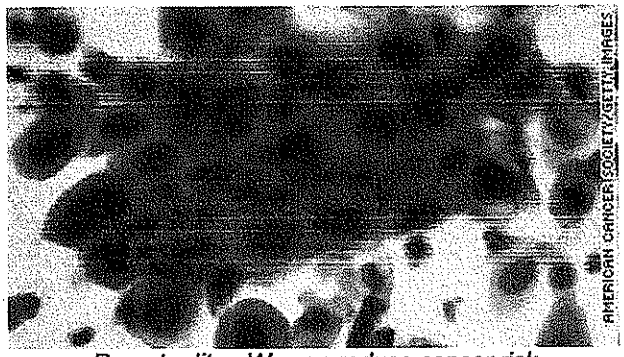
(CNN) -- Cancer cases are expected to surge 57% worldwide in the next 20 years, an imminent "human disaster" that will require a renewed focus on prevention to combat, according to the World Health Organization.

The World Cancer Report, produced by the WHO's specialized cancer agency and released on World Cancer Day, predicts new cancer cases will rise from an estimated 14 million annually in 2012 to 22 million within two decades. Over the same period, cancer deaths are predicted to rise from 8.2 million a year to 13 million.

The rising incidence of cancer, brought about chiefly by growing, aging populations worldwide, will require a heavier focus on preventive public health policies, said Christopher Wild, director of the International Agency for Research on Cancer.

"We cannot treat our way out of the cancer problem," he said. "More commitment to prevention and early detection is desperately needed in order to complement improved treatments and address the alarming rise in cancer burden globally."

The report notes that the rocketing cost of responding to the "cancer burden" -- in 2010, the economic cost of the disease worldwide was estimated at $1.16 trillion -- is hurting the economies of rich countries and beyond the means of poor ones.



Report editor: We can reduce cancer risk

The report said about half of all cancers were preventable and could have been avoided if current medical knowledge was acted upon. The disease could be tackled by addressing lifestyle factors, such as smoking, alcohol consumption, diet and exercise; adopting screening programs; or, in the case of infection-triggered cancers such as cervical and liver cancers, through vaccines.

"I know the report said we can't treat our way out of (the cancer problem) but there are major things we can do," said Dr. David Decker who works in oncology at Florida Hospital in Orlando. "Virtually 80 or 90 percent of lung cancers are caused by smoking. I know stopping smoking is not easy for people, but it does seem like a pretty simple way to reduce the numbers."

"The cancer rates are not going up for shocking reasons, but for reasons that are easier to understand, and if we improve overall health, there are things we can do to prevent this from happening," Decker said.

Cutting smoking rates would have a significant impact, as lung cancer remained the most commonly diagnosed cancer (1.8 million cases a year, or 13% of total cancer diagnoses) and the deadliest, accounting for about one-fifth (1.6 million) of all cancer deaths worldwide.

There is a silver lining to the report, some experts said: It may lend urgency to the fight against cancer. Countries such as the United States present examples of success stories stemming from legislation and financial resources devoted to cancer prevention.

"The good news is, in (the United States), cancer mortality is trending downward, and that would be more true if you make an age adjustment," said Dr. Walter Curran, chairman of the Department of Radiation Oncology at Emory University's School of Medicine in Atlanta.

"Since we have an aging population, the cancer rate increases, and if you adjust for the aging of America, the cancer rate is declining notably."

Curran said a typical 20-year-old American who doesn't smoke, "who has a good diet and a healthy lifestyle, someone with moderate alcohol consumption and who takes preventive health measures like regularly seeing a doctor and getting exercise -- their chance of cancer is significantly less than someone who for example lives in a developing country in Africa right now."

However, the United States is dealing with an obesity epidemic -- the rates of adults who are considered obese has doubled since the 1970s -- and drinking excessively is still the No.3 cause of lifestyle-related death.

Smoking is still the leading cause of preventable death in the United States. However, when the U.S. Surgeon General linked tobacco to lung cancer 50 years ago, more than 40% of the adult population smoked; now it's about 19%.

Public health initiatives have also made a difference in smoking rates. The report eventually spurred local governments to make it harder for a smoker to find a place to practice their habit. Many restaurants, bars, and even public parks ban smoking.

National leadership gave state governments license to raise taxes on cigarettes so much that people quit because they could no longer afford their habit.

Money from the federal tobacco lawsuit settlement went into smoking cessation programs and gave farmers incentives to grow crops other than tobacco. The FCC banned persuasive cigarette ads that may have encouraged young people to smoke.

Smoking rates remain high in Asia and Africa. China -- where one-third of the world's cigarettes are smoked, according to the World Health Organization -- only recently moved to ban indoor public smoking.

The report's authors suggested governments take similar legislative approaches to those they had taken against tobacco in attempting to reduce consumption of alcohol and sugary drinks, and in limiting exposure to occupational and environmental carcinogens, including air pollution.

According to the report, the next two most common diagnoses were for breast (1.7 million, 11.9%) and large bowel cancer (1.4 million, 9.7%). Liver (800,000 or 9.1%) and stomach cancer (700,000 or 8.8%) were responsible for the most deaths after lung cancer.

"The rise of cancer worldwide is a major obstacle to human development and well-being," said Wild, the International Agency for Research on Cancer director. "These new figures and projections send a strong signal that immediate action is needed to confront this human disaster, which touches every community worldwide."

The report said the growing cancer burden would disproportionately hit developing countries -- which had the least resources to deal with the problem -- due to their populations growing, living longer and becoming increasingly susceptible to cancers associated with industrialized lifestyles.

More than 60% of the world's cases and about 70% of the world's cancer deaths occurred in Africa, Asia, and Central and South America.

"In the developing world, we are really at the beginning of understanding how serious the cancer problem is in these countries," said Emory School of Medicine's Curran.

Cancers related to the HIV epidemic in developing countries and the spread of Hepatitis C are also on the rise, but so too is the general age of the population in developing counties. When you now have the potential to live long enough to see your grandchildren -- something that was not true even a decade ago in many developing countries -- your risk of having cancer is going to go up.

"When life expectancy get better, cancer rates will go up and so will cancer fatalities," Curran said.

Governments needed to appreciate that screening and early detection programs were "an investment rather than a cost," said Bernard Stewart, co-editor of the report -- and low-tech approaches had proven successful in some developing countries.

The World Cancer Report, which is published about once every five years, involved a collaboration of around 250 scientists from more than 40 countries. Tuesday is World Cancer Day.

READ: Samuel L. Jackson in new childhood cancer PSA

READ: Is lung cancer screening right for you?

READ: Surgeon general links colon cancer, diabetes to smoking

AuntMinnie.com

CMS bends on oncology PET coverage, will pay for 3 scans

By Brian Casey, AuntMinnie.com staff writer, Wayne Forrest, AuntMinnie.com staff writer

June 12, 2013 -- In a victory for PET proponents, the U.S. Centers for Medicare and Medicaid Services (CMS) on Tuesday issued a final decision on coverage of oncology FDG-PET scans, agreeing to pay for three follow-up studies rather than just one, as it had proposed three months ago.

In a final decision memo announcing the change, CMS said it was responding to comments received since it issued its proposed policy change in March to the national coverage determination (NCD) governing how Medicare pays for oncology FDG-PET scans. CMS had proposed paying for just one initial PET scan for oncology applications and one subsequent scan, with payment for any additional scans to be determined by local Medicare Administrative Contractors (MACs).

That proposal had drawn the ire of PET advocates, who believed that the lack of a national policy for oncology FDG-PET reimbursement could mean that many patients wouldn't get the scans even though they were clinically necessary for follow-up after therapy.

CMS said it received 175 comments opposing the one-scan limitation. Many of the respondents indicated that patients undergoing second- or third-line anticancer treatment typically receive three scans in the course of their therapy.

"CMS appreciates these comments and will nationally cover at least three additional scans," the agency wrote in its final decision memo. "Coverage of additional scans (that is, more than three) shall be determined by the local MACs."

The decision demonstrates the success of the National Oncologic PET Registry (NOPR), the body created in 2006 to serve as a vehicle for data collection on PET's effectiveness in changing the management of patients with solid tumors. Under the agency's coverage with evidence development program, PET sites were able to receive Medicare coverage for their studies only if they reported their data to NOPR. With this week's decision, PET sites will no longer have to participate in NOPR to receive FDG-PET reimbursement.

In the June 11 decision, CMS acknowledged that NOPR served its purpose well, gathering data on far more patients than were found in the more traditional clinical studies that the agency also reviewed in crafting its new policy. According to NOPR data, physicians reported that FDG-PET changed their management of patients by 35% to 40%.

At the same time, however, the agency found flaws in the NOPR process. For one, NOPR only recorded intended changes in patient management as reported by physicians, not actual changes. This limitation makes it impossible to determine whether the intended changes in management actually conferred a benefit in long-term patient outcomes, the agency wrote.

"Nevertheless, NOPR-derived results have informed our consideration of the evidence base for covering FDG-PET imaging for this oncologic indication," CMS wrote. "In the setting of anticancer treatment we believe that the choices made by treating physicians in many instances change the patient's experience of illness. Therefore we have largely accepted the persuasiveness of the NOPR report, except where we believe there is other evidence available to better support an alternative conclusion."

PET proponents also scored a victory by convincing CMS to back away from its initial decision not to include PET for prostate cancer in the list of covered clinical indications. In March, CMS said that clinical evidence did not support the use of FDG-PET for prostate cancer follow-up once therapy had been completed; instead, another radiopharmaceutical, choline-11, might be better suited.

In its final decision memo, however, the agency noted that it received public comments indicating that several more recent articles had demonstrated the value of FDG-PET scans for prostate cancer. CMS decided the modality was useful for determining the effects of treatment, particularly for progressive prostate disease.

Utilization growth?

Tuesday's decision memo also addressed the agency's concerns over an increase in PET utilization, particularly if asymptomatic patients were scanned for routine surveillance with no evidence of recurrence after their initial therapy. This fear was what had driven the agency to propose the one-scan limitation, CMS wrote.

might not be successful could be candidates for second-line or even further treatment, and for this reason, CMS decided to permit local Medicare contractors to determine coverage for additional FDG-PET scans beyond the initial three.

Upon hearing of the CMS edict late Tuesday at its annual meeting in Vancouver, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) applauded the agency's actions. SNMMI expressed hope that local Medicare contractors would agree to pay for more follow-up PET scans than just the three mandated by the new policy.

"We appreciate the fact that CMS has changed the limit from one scan to three," said SNMMI Vice President-Elect Dr. Hossein Jadvar, PhD, in a statement. "However, it will be important for the local contractors to allow more than three when clinically necessary."

SNMMI also supports the use of FDG-PET/CT to guide treatment for patients with prostate cancer as reasonable and necessary. "Monitoring metastatic prostate cancer therapy can be difficult," said SNMMI President Dr. Gary Dillehay. "However, in some indications PET can provide useful information for physicians in creating an effective treatment plan."

The society noted that PET sites must continue to work through the NOPR process to get reimbursement for sodium fluoride (NaF) scans. SNMMI "will continue working to develop evidence for NaF-PET through the NOPR program," Dillehay said.

Last Updated bc 6/12/2013 2:58:58 PM

Forum Comments

3 comments so far ...

6/13/2013 12:03:32 PM Atomtom	Is it CMS's intention that the 3 exams is a "lifetime" total?
6/13/2013 3:09:02 PM Sharp Rad	1. CMS criteria is still evolving, so lets not freeze or fret here. 2. There's a lot of clinical/ research/ [:@]administrative/ insurance Politics [:'(]and Gate-Management here at this point in time. 3. There has been some abuse on "repeat f/u PET/CT study", they probably picked such up on q3 or 4-month follow up repeat PET/CT imaging tendencies/ data-tracking stats, so they moved to close the loophole. 4. Its a freakin' money saving tactic (hello, read 'Bottomline Management'[8|] for ObamaCare by number crunchers or other jokers [:'(]), forced upon our Referring doc community that also affects Rad reads (repeat volume). 5. IMHO, these 'decision makers' dont really care about clinical outcome or patient well being as driving factor. They look at #s & $s. 6. We need to step up to the game, and have more of us Rads/ reasoning scientific Docs (those who want to do Admin/ get MHA/ MBA etc) among those who have a firm hold in directing medicine, its delivery, and its projected path. This is where we lack. Rare are the instances where a clinical MD is CEO/COO other than as a chosen pawn & rubber stamp they shamelessly deploy against ourselves/ us Rads/docs. 7. None of these 'gurus' actually practice medicine or presumably have had a family member's life taken by the politics of care delivery. 8. Gather up, my fellow Attendings, we need more of "us" amongst "them" :op .....reminds me of "Us and Them" / Pink Floyd, LOL
6/15/2013 7:46:59 AM BigDesk	*Quote from **Sharp Rad*** 1. CMS criteria is still evolving, so lets not freeze or fret here. 2. There's a lot of clinical/ research/ [:@]administrative/ insurance Politics [:'(]and Gate-Management here at this point in time. 3. There has been some abuse on "repeat f/u PET/CT study", they probably picked such up on q3 or 4-month follow up repeat PET/CT imaging tendencies/ data-tracking stats, so they moved to close the loophole. 4. Its a freakin' money saving tactic (hello, read 'Bottomline Management'[8|] for ObamaCare by number crunchers or other jokers [:'(]), forced upon our Referring doc community that also affects Rad reads (repeat volume). 5. IMHO, these 'decision makers' dont really care about clinical outcome or patient well being as driving factor. They look at #s & $s. 6. We need to step up to the game, and have more of us Rads/ reasoning scientific Docs (those who want to do Admin/ get MHA/ MBA etc) among those who have a firm hold in directing medicine, its delivery, and its projected path. This is where we lack. Rare are the instances where a clinical MD is CEO/COO other than as a chosen pawn & rubber stamp they shamelessly deploy against ourselves/ us Rads/docs. 7. None of these 'gurus' actually practice medicine or presumably have had a family member's life taken by the politics of care delivery. 8. Gather up, my fellow Attendings, we need more of "us" amongst "them" :op

Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4)

Decision Summary

A. The Centers for Medicare & Medicaid Services (CMS) is ending the requirement for coverage with evidence development (CED) under §1862(a)(1)(E) of the Social Security Act (the "Act') for ^{18}F fluorodeoxyglucose positron emission tomography (FDG PET) for oncologic indications which are contained in section 220.6.17 of the Medicare National Coverage Determinations Manual. This removes the requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for those cancers or cancer types that had been covered under CED (as listed in Appendix A).

B. CMS has determined that three FDG PET scans are covered under § 1862(a)(1)(A) when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anticancer therapy. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy will be determined by local Medicare Administrative Contractors.

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Decision Memo

TO: Administrative File: CAG # 00181R4

FROM: Louis Jacques, MD
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Medical Officer

SUBJECT: Decision Memorandum for Positron Emission Tomography (FDG) for Solid Tumors

June 11, 2013

DATE RELEASED:

I. Decision

A. The Centers for Medicare & Medicaid Services (CMS) is ending the requirement for coverage with evidence development (CED) under §1862(a)(1)(E) of the Social Security Act (the "Act') for ^{18}F fluorodeoxyglucose positron emission tomography (FDG PET) for oncologic indications which are contained in section 220.6.17 of the Medicare National Coverage Determinations Manual. This removes the requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for those cancers or cancer types that had been covered under CED (as listed in Appendix A).

B. CMS has determined that three FDG PET scans are covered under § 1862(a)(1)(A) when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anticancer therapy. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy will be determined by local Medicare Administrative Contractors.

II. Background

The scope of the first part of this reconsideration determination (described in paragraph IA above) is limited to those oncologic indications of FDG PET to guide subsequent anti-tumor treatment strategy, which had been covered only under CED. However, the scope of the second part of this reconsideration determination (paragraph IB above) includes any oncologic use(s) of FDG PET to guide subsequent antitumor treatment strategy, and specifically includes all types of solid tumors, not only those that had been covered under CED.

FDG PET is often performed using a device that combines FDG PET with other imaging modalities. Thus our evidence review includes reports derived from combination devices. Specifically, we include integrated FDG PET/computerized tomography (FDG PET/CT) and integrated FDG PET/magnetic resonance imaging (FDG PET/MRI) in the term FDG PET as used in this decision unless context indicates otherwise. However, we are not with this reconsideration determining any change in coverage either for CT or for MRI imaging.

Throughout this memorandum, we use the term FDG to refer to 2-deoxy-2-[^{18}F]-fluoro-D-glucose, also known as ^{18}F fluorodeoxyglucose. FDG is a radioactive tracer substance (radiopharmaceutical) that emits positrons as the radioisotope ^{18}F decays. We use the term PET more generally to refer to positron emission tomography or to a positron emission tomogram, depending on context. FDG PET refers to PET imaging utilizing FDG as the radioactive tracer. We use the abbreviation MBq to denote megabecquerel, a unit of radioactivity in the International System of Units (SI). We use the usual notation for denoting radioisotopes (e.g., ^{68}Ga for the gallium radioisotope with mass number 68, or ^{11}C for the carbon radioisotope with mass number 11). Atomic symbols are used infrequently for the elements they represent (e.g., Gd for gadolinium).

FDG PET is a minimally invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues such as cancers. As malignancies often have elevated rates of glucose metabolism, FDG PET imaging may indicate the probable presence of a malignancy based upon observed differences in glucose metabolic activity compared to adjacent tissue. Using co-registered ('integrated') PET/CT scanners (now in use in the overwhelming majority of PET centers (Hillner 2009 and Hillner 2012), FDG PET uses techniques to detect and count simultaneous gamma photons produced by ^{18}F decay, and also to assess the anatomic distribution of FDG.

Other diagnostic imaging technologies such as x-ray imaging, CT, and MRI primarily supply information about the anatomic features of suspected malignancies, such as their size, location, and relation to other organs or tissues. However, clinical imaging of glucose metabolism within tissues is unique to FDG PET technology. In many cases, while the anatomic information provided by CT or MRI is important in devising an initial or subsequent anti-tumor treatment strategy (ATS), the metabolic evidence provided by FDG PET imaging provides complementary information of value for ATS development.

For clarification, we use the phrase 'completion of initial anticancer therapy' to denote the conclusion of the first treatment regimen implemented for the elimination or control of a patient's cancer following its diagnosis. A treatment regimen could include multiple 'therapies' (such as chemotherapy, radiotherapy, and/or cancer surgery) in combination. Given this framework for anticancer therapy, the completion of initial anticancer therapy (that is, the conclusion or termination of all anticancer therapies in the initially intended (combination) treatment regimen) marks, in time, the starting point of subsequent ATS planning (and the completion of initial ATS planning). (Additionally, while we recognize that 'watchful waiting' represents a widespread clinical approach for patients with certain cancers, we do not intend that it is a 'therapy' to be included in an initial treatment regimen.)

III. History of Medicare Coverage

CMS has reviewed scientific literature and established coverage for many uses of FDG PET in oncology. See the CMS NCD Manual, Section 220.6, for currently covered indications at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf

Medicare coverage policies regarding FDG PET determine general and specific conditions of Medicare coverage for various indications. Some of these policies for oncologic indications specified CED, requiring prospective data collection used in initial treatment strategy and/or subsequent treatment strategy for oncologic indications.

A. Current Request

CMS was asked by the National Oncologic PET Registry (NOPR) to reconsider Section 220.6 of the NCD Manual to "end the remaining prospective data collection requirements under Coverage with Evidence Development (CED) for all oncology indications for FDG PET imaging." We have limited the scope of the first part of this reconsideration decision to those uses that had up to now been covered only under CED. The need for a second part of this decision (see paragraph IB above) became apparent as we considered the consequences of the first part. The second part of this reconsideration, in contrast, is intended to apply to all oncologic indications of FDG PET imaging.

. Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage §1812 (Scope of Part A); §1832 (Scope of Part B) and §1861(s) (Definition of Medical and Other Health Services) of the Act. FDG PET is considered to be within the following benefit category: other diagnostic tests §1861(s)(3). This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Medicare regulations at 42 CFR 410.32(a) state in part, that "...diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Thus, except where other uses have been explicitly authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

IV. Timeline of Recent Activities

September 12, 2012	CMS accepts a formal request to reconsider Section 220.6 of the NCD Manual to end the prospective data collection requirements across all oncologic indications of FDG PET. As tracking sheet was posted to the web site and the initial 30-day public comment period commenced.
October 12, 2012	The initial 30-day public comment period ended. Eighty-two comments were received
March 13, 2013	CMS posts the proposed decision memorandum. The second 30-day public comment period begins. The comment period was extended for two days due to a technical problem.
April 14, 2012	The second public comment period ends. CMS received 202 comments.

V. FDA Status

The FDA described the safety and effectiveness findings of FDG in a Federal Register notice dated March 10, 2000 (Volume 65, Number 48) Pages 12999-13010:

" ... The [FDA] Commissioner has concluded ... that FDG F 18 injection, when produced under the conditions specified in an approved application, can be found to be safe and effective in FDG PET imaging for assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities or in patients with an existing diagnosis of cancer, as discussed in section III.A.1 and III.A.3 of this document."

VI. General Methodological Principles

When making national coverage determinations, CMS generally evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the Agency generally uses to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B.

Public commenters sometimes cite the published clinical evidence and provide CMS with useful information. Public comments that provide information based on unpublished evidence, such as the results of individual practitioners or patients, are less rigorous and, therefore, less useful for making a coverage determination. CMS uses the initial comment period to inform the public of its proposed decision. CMS responds in detail to the public comments that were received in response to the proposed decision when it issues the final decision memorandum.

VII. Evidence

A. Introduction

Below is a summary of the evidence we considered during our review, primarily articles about clinical trials published in peer-reviewed medical journals. We considered articles cited in public comments, as well as those found by a CMS literature review. The agency also conducted a review of applicable professional society and other roup/organization statements, evidence-based practice guidelines and other relevant sources including recent texts of oncology. Citations are detailed below.

The Medicare regulations at 42 CFR 410.32(a) state in part, that "...diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Thus, we looked for evidence demonstrating how the treating physician uses the result of an FDG PET imaging test to inform subsequent anti-tumor treatment strategy (ATS) in beneficiaries with solid tumors who had completed initial anticancer treatment.

B. Discussion of Evidence Reviewed

1. Questions

a. *Is the evidence adequate to conclude that the results of an FDG PET scan will meaningfully improve health outcomes in beneficiaries who have completed an initial treatment regimen for any of the following types of solid tumors: brain, pancreas, prostate, soft tissue sarcoma, small cell (of lung), thyroid, testis, or for any other solid malignant tumor?*

We recognize that for diagnostic imaging, the following question is also pertinent if there is little evidence linking a test result directly to health outcomes.

b. *Is the evidence adequate to conclude that the results of an FDG PET scan will guide physician management of subsequent anti-tumor treatment strategy in beneficiaries who have completed an initial treatment regimen for any of the following types of solid tumors: brain, pancreas, prostate, soft tissue sarcoma, small cell (of lung), thyroid, testis, or for any other solid malignant tumor?*

2. External Technology Assessments

CMS did not request an external technology assessment (TA) on this topic. However, CMS is aware of two external technology assessments relevant to this topic.

The first is a 2010 Special Report from the Blue Cross Blue Shield Technology Evaluation Center (BCBS/TEC) on the topic of PET for post-treatment surveillance of cancer. In that report 'surveillance', as it applies to patients after completion of initial anticancer therapy, means the use of FDG PET "in the absence of signs or symptoms of cancer recurrence or progression, for the purpose of detecting recurrence or progression or predicting outcome." (BCBSA 2010, p. 1) This special report was published in cooperation with Kaiser Foundation Health Plan and Southern California Permanente Medical Group. The BCBS/TEC report indicated that "(t)here is simply inadequate direct and indirect evidence supporting the efficacy of PET scanning for the purpose of surveillance. Reflecting this lack of evidence, current practice guidelines appear unanimously to recommend against the use of PET for surveillance. No strong support of the use of PET for surveillance was found in editorials, case reports, or other studies. ... Clinical trials may be necessary to determine whether PET surveillance is effective in improving health outcomes." (BCBSA 2010)

The second external technology assessment is from the United Kingdom (UK), entitled "Overview of the clinical effectiveness of positron emission tomography imaging in selected cancers" (Facey 2007). The authors reviewed the literature to late 2005 on FDG PET, and surveyed PET centres in the UK. The report concluded that "(t)he strongest evidence for the clinical effectiveness of FDG PET is in staging NSCLC (non-small cell lung cancer), restaging HL (Hodgkin lymphoma), staging/restaging colorectal cancer and detection of SPN (solitary pulmonary nodule). Some of these may still require clinical audit to augment the evidence base. Other management decisions require further research to show the impact of FDG PET on patient management or added value in the diagnostic pathway." As noted above, this technology assessment reached conclusions on clinical effectiveness of indications for FDG PET on types of cancers already covered nationally by the Medicareprogram in the United States.

3. Internal technology assessment

The reviewed evidence was gathered from articles submitted by the requesters, cited in public comments during a public comments period (mid-December 2012 through mid-January 2013) and from a literature search of the PubMed database by CMS staff in December 2012 and January 2013.

Literature search methods

CMS staff used PubMED to search for relevant peer-reviewed articles published in the medical literature. The following search terms were used: "FDG PET", "cancer" or "soft tissue sarcoma", "subsequent" or "subsequent treatment strategy", and either "recurrence" or "response" for each tumor type listed above. The CMS internal search was limited to articles published in the last five years (i.e., published after the most recent prior reconsideration of this topic) about results of clinical trials involving adult human subjects; to reports of randomized and non-randomized controlled trials, cohort studies, and case series meeting certain criteria; and to articles published in English. Also, clinical trials were excluded from further review if:

- fewer than ten patients were studied;
- the type of cancer studied is currently nationally covered for FDG PET imaging without requiring data collection;
- the cited article did not indicate whether an initial treatment plan had been completed, or whether an FDG PET scan was performed after completion of the initial treatment plan; or
- the study was related to costs or cost-effectiveness of FDG PET imaging, or was based on a simulation or decision modeling approach rather than patients' actual outcomes.

CMS staff reviewed full-text versions of articles suggested by the requesters or cited in public comments. The usual CMS criteria for evidentiary value were used (please see Appendix B). In addition, any relevant article indexed by PubMED as 'Review' or 'Guideline' or 'Health-services research' was used only for background information and is listed in the Bibliography.

Summaries of articles about clinical trials are grouped below by:

1. trial design (as listed in decreasing order by evidentiary value (see Appendix B));
2. last name of first author in ascending alphabetical order; and
3. year of publication in reverse chronologic order.

Studies with the same first author in the same year of publication are distinguished by a one-letter suffix (e.g., 2011*A*, 2011*B*, etc.)

Prospective controlled trials

Garrett CR, Siu LL, El-Khoueiry A, et al. Phase I dose-escalation study to determine the safety, pharmacokinetics and pharmacodynamics of brivanib alaninate in combination with full-dose cetuximab in patients with advanced gastrointestinal malignancies who have failed prior therapy. Br J Cancer. 2011; 105(1):44-52.

This study of a new treatment agent for advanced gastrointestinal malignancies in patients who had failed prior therapy included a secondary objective of assessing the reproducibility of FDG PET measurements of SUV parameters in this multi-center trial. Eighty-five patients enrolled in the study included 61% males and 39% females, and their median age was 60 years. Most (59/61 who passed screening for treatment suitability) had colorectal cancer; two had esophageal cancer, and one had fibrolamellar hepatoma. Most frequent sites of metastases were liver (in 53 patients), lung (in 51) and lymph node (in 19). Results of the FDG PET analysis indicated that the percent difference of SUVmax as measured in the two baseline scans ranged from -34% to 52% (data not shown). The authors commented that metabolic response may represent a predictive marker of clinical outcomes.

Ruers TJ, Wiering B, van der Sijp JR, et al. Improved selection of patients for hepatic surgery of colorectal liver metastases with (18)F-FDG PET: a randomized study. J Nucl Med. 2009; 50(7): 1036-41.

In this randomized clinical trial, 150 patients with colorectal cancer metastases to the liver were randomized 1:1 to either the CT group or the CT and PET/CT imaging prior to surgery group. The mean age of patients was about 62.7, and 46 females and 104 males participated. The patients in each group were comparable at baseline, based on age, gender, stage of primary tumor, size and number of hepatic tumors, preoperative CEA, and other criteria. A laparotomy that did not allow for complete treatment of metastases, which revealed benign disease, or which resulted in less than six months' subsequent survival, was considered futile. The authors found that there were 34 (45%) futile laparotomies in the study arm with preoperative CT only, and 21 (28%) futile laparotomies in the study arm with preoperative FDG PET/CT and CT. The relative reduction in risk of futile laparotomies was 38% (4 -60%), with p=0.042. The authors concluded that adding FDG PET/CT to the presurgical evaluation workup prevented unnecessary surgery in (31-24)/75 or ~17% of patients (approximately one in six patients). However, during a followup period of up to 3.5 years, there was no significant difference found in overall survival between the control (CT only) and experimental (CT + PET) groups. The authors suggested, based on some research studies, that further studies of MRI for preoperative evaluation might further decrease futile laparotomies.

rospective cohort studies

Benz MR, Herrmann K, Walter F, et al. FDG PET/CT for monitoring treatment responses to the epidermal growth factor receptor inhibitor erlotinib. J Nucl Med. 2011 (Nov); 52(11): 1684-9.

In their 2012 published article, Benz and colleagues prospectively studied whether early changes in tumor uptake of FDG, as measured by FDG PET/CT, can predict progression free and overall survival in non-small-cell lung cancer (NSCLC) treatment with erlotinib, a tyrosine kinase inhibitor that acts on the epidermal growth factor receptor (EGFR). 22 patients, age older than 18 years, with Stage IIIB or IV, who were scheduled to receive erlotinib, were recruited for this study. A baseline FDG PET/CT study was obtained a median of three days (range, 0 to 32 days) before start of erlotinib treatment ('ET'). This was followed by an 'early followup' FDG PET/CT study 14 +/- one day after initiation of ET. Eleven patients also underwent a third FDG PET/CT study 78 +/- 21 days after the start of ET (in the other eleven patients, ET therapy was discontinued before the third scan could be obtained). Study endpoints were progression-free survival (PFS) and overall survival (OS) of metabolic responders and non-responders. Metabolic responders were defined as complete (complete resolution of FDG uptake by tumor), partial (reduction of at least 30% in tumor FDG uptake), progressive disease (increase of a minimum of 30% in tumor FDG uptake or presentation of a new lesion), or stable metabolic disease (not complete or partial responses or progressive disease) on the basis of SUV calculated within the tumor volume (not, as the authors noted, as tumor SUVmax). Up to five lesions were assessed in any patient. The authors found that of the 22 patients, 16 were female, and six were male. 45% had a history of smoking. The study population included 14 Caucasians, six Asians, and two patients of other racial groups. The histologic types of the cancers included adenocarcinomas (77%), squamous cell carcinomas (14%), large cell carcinomas (4%) and unspecified cancers (4%). 19 of 22 patients (86%) had Stage IV disease at enrollment. 15 of 22 patients had prior therapy of som type, including two with resection as part of their treatments. Early response PET studies classified 6/22 (27%) patients as complete or partial responders, 7/22 (32%) patients as stable disease, and 9/22 (41%) patients as progressive disease. The median overall survival (OS) duration was 131 days (95% CI, 0-351 days). Patients classified as progressive disease on 'early' FDG PET/CT scans showed significantly ($p=0.03$) shorter OS than patients classified in other categories. The authors acknowledged some limitations of the study, including the high proportion of women, who tend, as never-smokers, to be more responsive to EGFR inhibitors such as erlotinib. Also, the study may have included patients whose EGFR mutations (which were not tested) might have affected response to treatment. Another possible interaction source may have affected response in patients on combination therapy, i.e., in the five (23%) of 22 patients treated with estrogen receptor or anti-inflammatory drugs, the effects of which might have affected FDG uptake. Additional research was suggested in larger patient populations.

Enslow MS, Zollinger LV, Morton KA, et al. Comparison of FDG and F-18 fluorothymidine PET in differentiating radiation necrosis from recurrent glioma. Clin Nucl Med. 2012 Sep; 37(9): 854-61.

Based on a prospective case series of patients with histologically proven primary malignant gliomas post radiation and/or chemotherapy, the authors investigated whether new enhancing lesions in the radiation field (as demonstrated on Gadolinium magnetic resonance imaging (Gd-MRI)) could be identified as recurrent tumor or as radiation necrosis by either FDG or ^{18}F fluorothymidine (FLT) PET studies. All scans were conducted according to study-specific protocols. Exclusion criteria included: pregnancy or lactation; signs of uncal herniation; prior reactions to administered radiopharmaceuticals; and requiring monitored anesthesia for PET scanning. PET images were interpreted by two experienced readers. Recurrent tumor was defined by definitive increase in size of the enhancing lesion on Gd-MRI as interpreted by a neuroradiologist, while radiation necrosis was defined by stability or regression of the enhancing lesion over time. The authors found that of 15 enrolled patients, nine were male and six were female, and their ages ranged from 22-75 years. Radiation therapy had been completed four or more months prior to study entry. Ten patients had glioblastoma multiforme (GBM); three had grade III oligodendroglioma; one had grade II astrocytoma, and one had oligoastrocytoma. Based on longitudinal Gd-MRI, eleven patients had recurrent tumor, while four had radiation necrosis, including three patients with GBM, and one with grade II astrocytoma. The authors also found a statistically significant difference between FDG SUVmax for recurrent tumor (mean 8.2, range 5.3-12.1) and that for radiation necrosis (mean 5.5, range 4.3-6.5) (p = 0.019, Kruskal-Wallis one-way analysis of variance). A summary table (Table 2) described the performance characteristics of the different methods:

Adapted from Table 2 of Enslow 2012:

Parameter	FDG	FDG ratio	F-18 FLT	FLT Ki-max
Area under ROC curve	0.93	0.98	0.86	0.89
95% CI	0.75 – 1.00	0.91 – 1.00	0.56 – 1.00	– 1.00
Optimized cut-off for tumor	6.20	1.83	1.34	0.0165

The authors concluded that, although quantitative determinations of FDG uptake allow accurate differentiation of recurrent glioma from radiation necrosis, ^{18}F FLT had no striking advantage as a radiopharmaceutical for this indication over FDG PET.

Gayed I, Vu T, Iyer R, et al. The role of ^{18}F FDG PET in staging and early prediction of response to therapy of recurrent gastrointestinal stromal tumors. J Nucl Med. 2004 Jan; 45(1): 17-21.

This study compared the roles of FDG PET and CT in follow-up of gastrointestinal stromal tumors (GISTs) after treatment with imatinib mesylate. Forty-nine patients with GIST underwent FDG PET and CT within three weeks of starting imatinib therapy, and repeat scans two months after therapy. Fifty-four patients (23 women and 31 men) with a mean age of 56.4 years (range 30-82 years) were included in this study. Patients who had previously undergone chemotherapy or radiation therapy or had a second type of cancer were excluded. Five lesions outside the CT field were also excluded from analysis. True positive lesions were defined as those in which FDG PET and CT results were in agreement, or when alternate diagnostic tests were positive for the presence of malignancy, including evidence of progression on subsequent diagnostic imaging studies. False positive and false negatives were also defined by discordant findings of other diagnostic modalities or follow-up studies. Patients undergoing FDG PET scanning followed a standardized preparation protocol and dosing amount after blood glucose was checked. FDG PET scans covered the base of the skull through the mid-thighs. CT scans extended from the thoracic inlet through the ischial tuberosity. Criteria for response to therapy or disease progression included, for FDG PET, either a more than 25% increase or decrease in SUVmax, and for CT, a decrease of 5% or more in longest dimension or an increase of greater than 5% in longest dimension. Intermediate values of FDG PET SUV or CT longest dimensions were considered to show 'stable disease'.

The authors found that, in the 49 patients with repeated CT and FDG PET studies at two months, both types of scans showed responses to treatment in 28 (57%). Of these 28 patients, 17 experienced clinical improvement, while eleven remained asymptomatic. SUVmax decreased to background levels in 25/28 patients, and by at least 30% in the remaining three patients. In contrast, seven (14%) of forty-nine patients showed no response on either FDG PET or CT scans. Of these seven, six had no clinical change in symptoms, while one patient experienced deterioration. Discrepant results between FDG PET and CT scans were noted in 14 (29%) of 49 patients. Longer follow-up showed that FDG PET (on average, after 8.2 months) correctly predicted response to therapy earlier that CT in ten (71%) of 14 patients. The authors concluded that CT and FDG PET studies have comparable sensitivity and positive predictive value in staging recurrent malignant GISTs. FDG PET was found to be superior in predicting early response to therapy (i.e., at two months after initiation of imatinib treatment).

Hillner BE, Siegel BA, Hanna L, et al. Impact of FDG PET Used After Initial Treatment of Cancer: Comparison of the NOPR 2006 and 2009 Cohorts. J Nucl Med. 2012 May; 53(5): 831-7. (Hillner 2012)

NOTE: This was also submitted as a reference with NOPR's current request.
This prospective cohort study compared data on FDG PET studies performed for oncologic indications in two groups of Medicare beneficiaries: those enrolled from May 8, 2006 – April 3, 2009 ('2006 cohort'); and those enrolled from April 4, 2009 – November 30, 2011 ('2009 cohort'). For each patient in both cohorts, a before-FDG PET and after-FDG PET design examined physicians' intended management decisions for cancer patients. The 'after-FDG PET' data collection sought data from participating physicians about their impressions of the extent of disease in all patients (more extensive, unchanged, or less extensive than before PET results were known); and, for patients on chemotherapy, to record their assessment of the patient's prognosis (better, unchanged, or worse given the PET findings) and their intentions for patient management. The authors categorized decisions as 'treatment' (e.g., surgery, chemotherapy, radiation, or other active cancer treatment) or 'non-treatment' (e.g., observation, alternative imaging, or other non-invasive therapy, biopsy, or supportive care). For patients in the 2009 cohort receiving cancer chemotherapy, endpoints also included continuing, modifying, switching, or stopping chemotherapy. Statistics on the number of patients in whom intended therapeutic strategy changed after FDG PET (from treatment to non-treatment, or vice-versa) were aggregated and compared for each cohort, stratified by cancer type.

The authors found that 90% of participants were 65 years of age or older (younger participants were disabled beneficiaries). FDG PET studies were performed using integrated scanners in more than 90% of participants in both cohorts. Among patients undergoing FDG PET studies for chemotherapy monitoring, about 6% had less than one month of therapy; 32% had one to three months; 28% had three to six months; and about one-third had more than six months of treatment. About 70% of the time after PET findings, physicians changed patients' prognoses. This conclusion did not 'meaningfully' change from the 2006 to the 2009 cohort. A better prognosis than anticipated occurred in about 40%; prognosis was unchanged in 31%; and worse in 29%.

The table below shows the changes in intended management associated with FDG PET for some of the cancer types in this cohort, when used in restaging in beneficiaries over age 65.

Table (adapted from Table 3 of Hillner 2012):

Cancer Type	NOPR Cohort	Patients (n)	% Change in intended management	95% Conf. Int.
Pancreas	2006	2,876	40.2	38.4 – 42.0
	2009	4,238	40.0	38.6 – 41.5
Prostate	2006	4,856	37.8	36.5 – 39.2
	2009	5,465	41.4	40.0 – 42.7
Small cell, lung	2006	2,810	40.7	38.9 – 42.6
	2009	5,403	40.2	38.9 – 41.5
All other cancers	2006	5,280	34.3	33.0 – 35.6
	2009	15,466	33.4	32.7 – 34.2
Totals	**2006**	**27,860**	**35.8**	**35.3 – 36.4**
	2009	**48,831**	**35.9**	**35.4 – 36.3**

The authors also found that for the subset in each cohort of patients receiving cancer chemotherapy, PET results changed physicians' intentions to continue, switch, adjust, or stop chemotherapy ('ChemoRx') in about half of all patients, as shown in the following table.

Table (adapted from Table 4 of Hillner 2012):

Cancer Type	NOPR Cohort	Patients (n)	Switch ChemoRx (%)	Adjust ChemoRx (%)	Stop ChemoRx (%)
Pancreas	2006	1,783	26.8	15.2	13.1
	2009	2,198	25.0	6.9	13.5

Cancer Type	NOPR Cohort	Patients (n)	Switch ChemoRx (%)	Adjust ChemoRx (%)	Stop ChemoRx (%)
Prostate	2006	1,024	25.5	14.2	19.6
	2009	1,336	30.1	7.8	14.1
Small cell, lung	2006	1,346	28.9	15.4	20.5
	2009	2,083	24.1	4.8	19.0
All other cancers	2006	2,100	25.6	13.8	19.1
	2009	4,387	25.6	6.5	16.8
Total	**2006**	**10,234**	**26.7**	**14.6**	**18.6**
	2009	**15,611**	**25.9**	**6.3**	**16.3**

The authors concluded that, when used for subsequent ATS, an FDG PET scan was associated with about a 35% change in intended management of study participants. The observed intended management changes were minimally different between cancer types, cohorts, and age groups (i.e., when comparing younger (disabled) beneficiaries with those of 65 years of age or older).

The authors noted that when FDG PET scans were used for assessing response to chemotherapy (representing the indication for about 22% of FDG PET scans performed on study participants) there were some reasons to be cautious in using this study to assess FDG PET scans' utility. For example, although the authors mention that for treatment monitoring, a baseline image is often required for comparison, NOPR did not require that a preceding FDG PET scan be available; nor were the rates or timings of prior scans assessed in this study.

The authors further noted that, for participants who had already received six months or more of chemotherapy before FDG PET imaging, it was uncertain if these 'treatment monitoring' scans might have instead been classified instead as 're-staging' depending on how they may have been categorized by the referring physician.

The authors pointed out that the principal impact of FDG PET on management during chemotherapy occurred in patients whose FDG PET scans showed more extensive disease or a worse prognosis that was anticipated. In these patients, physicians indicated they intended to continue chemotherapy without modification in only about 10% of patients for whom FDG PET indicated a worse-than-anticipated prognosis.

Separately, the authors suggested that, because the results based on the NOPR 2009 cohort data, including more than 70,000 PET studies, have shown little difference from those derived from data on the NOPR 2006 cohort, extension of data collection under NOPR may not provide much additional insight into how FDG PET affects intended clinical management in oncology. Instead, the authors suggested that further studies designed to compare and assess the roles of advanced imaging at several key decision points in 'real-world' clinical cancer care may be needed.

Hillner BE, Siegel BA, Shields AF, et al. Impact of dedicated brain PET on intended patient management in participants of the NOPR. Mol Imaging Biol. 2011; 13: 161-5. (Hillner 2011)

NOTE: This was also submitted as a reference with NOPR's current request.
The authors examined the demographic characteristics and changes in intended management after FDG PET scanning in patients in NOPR patients with brain tumors. The authors described their interest in assessing the role of FDG PET, both to determine tumor progression after therapy and to distinguish between radiation necrosis and tumor. Brain PET scans done between December 2006 and April 2009 were eligible for inclusion in this study. The authors found that of 274 brain PET scans done in participants with primary brain tumors, 61 were for the indication of restaging, and 213 were for detection / confirmation of suspected recurrences. Participants receiving brain PET scans in NOPR were found to be younger than NOPR cases overall (41.3% younger than 65 years vs. 10.5% overall). The authors also found that changes from treatment to non-treatment were more frequently seen in those with primary brain tumors than in the overall NOPR cohort (13.4% vs. 7.7% (OR 1.9, 95% CI 1.3-2.5)). The authors commented that, although PET scanning of primary brain tumors has limited sensitivity due to the background of high glucose avidity of normal gray matter, and accounts for only 0.67% of all NOPR cases, PET scans were informative about tumor grade and persistent or recurrent disease after therapy. The authors also suggested that referring physicians were selective in ordering PET scans infrequently to evaluate metastatic cancers to the brain.

Hillner BE, Siegel BA, Shields AF, et al. The impact of PET on expected management during cancer treatment: findings of NOPR. Cancer 2009 Jan 15; 115: 410-8. (Hillner 2009)

NOTE: This was also submitted as a reference with NOPR's current request.

This prospective cohort trial, based on NOPR data, reported on the impact of FDG PET on intended management of patients with cancer of any type except breast cancer. NOPR organization and study design had been previously described elsewhere. The endpoint in this analysis was the changes in referring physicians' decisions about intended therapy, before and after FDG PET results on their patients. Included in this study were those participants enrolled in NOPR from May 8, 2006 through December 31, 2007 with a PET scan for treatment monitoring. Excluded were those with FDG PET studies of cancer types already covered or non-covered by Medicare, or with oncologic indications other than treatment monitoring. The authors found that of the 10,247 participants in this study group, the mean patient age was 71.8 years, and 52% of these participants were female. Cancer types among these NOPR participants included ovary and uterine adnexa, pancreas, lung (all types), prostate, myeloma, bladder, stomach, colon, kidney and other urinary tract, lymphoma, and other. More than 90% of NOPR participants were scanned using an integrated PET/CT scanner. Most (72%) were studied at non-hospital based imaging centers. 83% had an Eastern Cooperative Oncology Group (ECOG) score of 0 (asymptomatic, fully active) or one (symptomatic, fully ambulatory). Types of therapy being monitored included chemotherapy in 81.7% of participants; radiation therapy in 6.2%; and combination therapy in 12.1%. The following table shows the impact of PET results on intended management: nearly half of participating physicians' post-PET plans changed therapy for their cancer patients.

Table (adapted from Table 3 of Hillner 2009):

Post-PET Plan	Participants (%)
No change in therapy	5321 (50.7%)
Switch to another therapy	2778 (26.5%)
Adjust dose or duration of therapy	1744 (16.6%)
Change to observation or supportive care plan	654 (6.2%)

The authors also found that the treatment plan was unchanged in only 21.4% of patients whose FDG PET scans indicated a worse prognosis. Finally, the authors noted that on the post-PET data collection form, physicians indicated that FDG PET results enabled them to avoid additional tests or procedures after 90.6% of scans.

The authors noted, among limitations of this study, that by design it collected data on 'intended' rather than 'actual' patient management decisions by participating physicians. A different design such as a prospective controlled clinical trial might allow a more nuanced examination of actual patient management changes after FDG PET scanning, as well as assess impact of FDG PET scanning on long-term outcomes.

Hillner BE, Siegel BA, Liu D, Shields AF, Gareen IF, Hanna L, Stine SH, Coleman RE. Impact of PET/CT and PET alone on expected management of patients with cancer: initial results from the NOPR. J Clin Oncol. 2008 May 1; 26(13): 2155-61. (Hillner 2008A)

NOTE: This was also submitted as a reference with NOPR's current request.
This article presented the findings of the first assessment of NOPR data to determine the impact of FDG PET results on intended management of Medicare beneficiaries with cancer. The design and procedures of NOPR have been described previously. The authors found that 22,975 cases were eligible for study inclusion and included complete records for analysis. The mean patient age was 72.9 years; participants included nearly equal proportions of women and men (49.9% / 50.1% respectively); and about 10% of the cohort were patients younger than 65 years eligible for Medicare coverage on the basis of disability. The indication for FDG PET scanning in 24.4% of participants was restaging following treatment; in 23.5%, the indication was to detect/confirm suspected cancer recurrence. To examine the effect of FDG PET scans on intended management for subsequent antitumor treatment strategy, the table below shows the proportion of cases of cancers of all types with changes in intended management when FDG PET scans were performed for the indications of restaging and confirmation/detection of recurrence:

Table (adapted from Table 2 of Hillner 2008A):

Indication:	**Changes in Intended Management, All Cancer Types (Percentages of cases (95% C.I.))**
Restage	36.1 (34.9 – 37.4)
Confirm/Detect Recurrence	38.9 (37.6 – 40.2)

The authors commented that the NOPR-based studies were valuable in focusing on the effect of an advanced imaging technology on intended physician management decisions, in contrast with other types of clinical trials with patient survival as their most relevant outcome. They also comment that the values of their findings are strengthened by the substantial size of the data set examined, its national scope, and the completeness of data collection. Limitations noted by the authors include the absence of actual patient outcome data, and the unknown contribution of FDG PET or FDG PET/CT compared to those of other imaging modalities. Further research was suggested.

Hillner BE, Siegel BA, Shields AF, et al. Relationship between cancer type and impact of PET and PET/CT on intended management: findings of NOPR. J Nucl Med. 2008 Dec; 49(12):1928-35. (Hillner 2008B)

NOTE: This was also submitted as a reference with NOPR's current request.
This article presents the findings derived from the first two years' data collected by the NOPR. The impact of FDG PET on different oncologic indications by cancer type is presented for patients registered from May 8, 2006 through May 7, 2008. The study included consenting Medicare beneficiaries (and their referring physicians) with FDG PET scans for, among other indications, restaging and detection of recurrences of cancers that were not either nationally covered or nationally non-covered by CMS. Analyses of post-PET changes of intended therapy (treatment to non-treatment or vice versa) were performed for both restaging and detection of recurrences and were separately performed by cancer type. The authors found that the final analysis cohort for this article consisted of 40,863 scans on 34,536 participants. The mean patient age was 72.4 years, with nearly equal numbers of men and women (49.8% / 50.2% respectively). 16 cancer types had at least 500 cases each in the registry, and the total of the number of cases for all 16 types represented about 90% of all registry cases.

For the indication of restaging, the following table shows, by cancer type, the % of cases with change in intended management:

Table (adapted from Table 6 of Hillner 2008B):

Cancer Type (number of scans)	Percentages of cases with changes in intended management
Ovary (1,971)	37.7
Prostate (1,477)	34.0
Small cell, lung (1,357	40.8
Bladder (1,239)	36.4
Uterus (1,064)	30.5

Cancer Type (number of scans)	Percentages of cases with changes in intended management
Pancreas (1,021)	38.3
Myeloma (1,009)	46.4
Kidney (979)	34.4
Stomach (916)	35.5
Connective tissue (450)	28.0
Skin, non-melanoma (363)	23.1
Cervix (353)	26.9
Liver and intrahepatic bile ducts (260)	41.9
Leukemia (229)	36.7
Gallbladder (215)	38.6

Cancer Type (number of scans)	Percentages of cases with changes in intended management
Thyroid (203)	34.5
All other (1,478)	33.2
Total (14,584)	**35.9**

For the indication of detection of recurrence, the following table shows, by cancer type, the % of cases with change in intended management:

Table (adapted from Table 7 of Hillner 2008B):

Cancer Type (number of scans)	Percentages of cases with changes in intended management
Ovary (2,160)	44.5
Prostate (1,790)	39.4
Uterus (1,059)	38.8
Kidney (1,003)	32.4
	36.7

Cancer Type (number of scans)	Percentages of cases with changes in intended management
Bladder (878)	
Pancreas (802)	39.3
Stomach (553)	29.3
Small cell, lung (544)	38.1
Myeloma (373)	50.9
Connective tissue (366)	34.7
Cervix (290)	35.9
Thyroid (253)	33.2
Primary brain (222)	40.5
Other female genital (206)	39.8
All other (1,415)	35.1

Cancer Type (number of scans)	Percentages of cases with changes in intended management
Total (11,914)	38.5

The authors concluded that based on physician records of intended subsequent antitumor treatment strategy, FDG PET results change intended management for a variety of common cancer types. The authors also calculated that, based on national incidence figures, the NOPR cohort included from 10 – 20% of patients with these types of cancers.

Kitajima K, Murakami K, Yamasaki E, et al. Performance of integrated FDG PET / contrast-enhanced CT in the diagnosis of recurrent pancreatic cancer: comparison with integrated FDG PET / non-contrast enhanced CT and enhanced CT. Mol Imaging Biol. 2010; 12: 452-9.

In this prospective study, the authors evaluated the accuracy of FDG PET/CT with intravenous contrast for detection of recurrent pancreatic cancer. Fifty patients who had undergone surgery for histopathologically proven pancreatic cancer with suspected recurrent and/or metastases were recruited to undergo FDG PET/CT (contrast-enhanced and non-enhanced) at one institution. Five patients were dropped from further analysis due to lack of follow-up information. A standard protocol was used in performing PT scans on all patients. Contrast-enhanced CT was retrospectively evaluated in consensus by two experienced radiologists who had no knowledge of either the other imaging results or of the clinical data. FDG PET/contrast-enhanced CT images were interpreted by two other experienced radiologists, also unaware of other imaging results or of clinical data. The reference standard for diagnosis was histopathologic examination after surgery or biopsy (n=21), or clinical follow-up of at least six months (range, 6 – 26 months) with a rising tumor marker (CA 19-9). The authors found that the mean patient age was 58 years, with a range of 45-81 years. The treatment included: surgery plus chemotherapy in 28/45 patients; surgery only in 14/45 patients; and surgery plus chemoradiotherapy in three of forty-five patients. Reasons for seeking the FDG PET/CT study included: an abnormal serum tumor marker (in 22/45 patients); an abnormal conventional imaging study (in seven); both in twelve patients; and an abnormal physical examination in four. Time between the last treatment and the study FDG PET/CT showed a mean of nine months and a range of four to twenty months. The authors found that in 24/45 patients, recurrence or distant metastasis were confirmed by pathologic examination. In 21/45 other patients, absence of recurrence was indicated by pathologic examination (n = 2), follow-up tumor marker and FDG PET/CT confirmation scans (n=9), and CA 19-9 levels with contrast-enhanced CT imaging (n=10). The following table (adapted from their Table 3, p. 457) compares FDG PET/CT (enhanced) and PET/CT (unenhanced) findings in patients with and without recurrence:

Table (adapted from Kitajima 2010, Table 3)

Imaging	TP	FN	TN	FP	Sensitivity	Specificity	PPV	NPV	Accuracy
CT	16	8	18	3	67%	86%	84%	69%	76%

Imaging	TP	FN	TN	FP	Sensitivity	Specificity	PPV	NPV	Accuracy
PET/CT (non-enhanced)	20	4	19	2	91%	91%	91%	83%	87%
PET/CT (enhanced)	22	2	20	1	95%	95%	96%	96%	93%

The authors found no significant difference in accuracy between FDG PET with and without contrast-enhanced CT (McNemar test: $p = 0.083$). They concluded that FDG PET/CT (contrast-enhanced) was a valuable and potentially 'first-line' diagnostic tool for assessing patients with suspected recurrence of treated pancreatic cancer. The authors mentioned the limitations of the study, including the lack of histologic confirmation of all cases of recurrence as a reference standard, the relatively small number of patients studied, and the lack of a separate CT scan with which to compare diagnostic accuracy with FDG PET/CT.

Lordick F, Ott K, Krause BJ, Weber WA, Becker K, Stein HJ, Lorenzen S, Schuster T, Wieder H, Herrmann K, Bredenkamp R, Höfler H, Fink U, Peschel C, Schwaiger M, Siewert JR. PET to assess early metabolic response and to guide treatment of adenocarcinoma of the esophagogastric junction: the MUNICON phase II trial. Lancet Oncol. 2007; 8(9):797-805.

In this study, the authors attempted to evaluate a PET-guided strategy to individualize therapy for patients with locally advanced adenocarcinoma of the esophagogastric junction (AEG). 119 patients were recruited into this prospective, single-center study. Patients were considered 'responders' if they showed a 35% or greater decrease in SUV by the FDG PET/CT study at the end of the treatment evaluation period (ie, after two weeks of platinum and fluorouracil induction therapy). Responders continued chemotherapy and then underwent surgery; non-responders proceeded to surgery. The primary endpoint was median overall survival of both responders and non-responders. The authors found that 110 patients could be evaluated for responder/non-responder status. 54/110 (49%, 95% CI of 39-59) were found to be responders. After a median follow-up of 2.3 years, median overall survival was not determined among responders, while non-responders had a median OS of 25.8 months (HR 2.13, 1.13-3.99, p = 0.15). Major histologic response was seen in 29 of 50 responders, but in none of the non-responders (p = 0.001)). The authors commented that use of a 35% decrease in SUV as the criterion for response was associated with a higher predictive value for histological response, and suggested that randomized clinical trials would be needed to determine the clinical relevance of this study.

Meirelles GS, Schoder H, Ravizzini GC, et al. Prognostic value of baseline [18F]-fluorodeoxyglucose positron emission tomography and 99mTc-MDP bone scan in progressing prostate cancer. Clin Cancer Res. 2010; 16:6093 -6099.

In this article, the authors prospectively investigated the value of SUVmax in FDG PET scans in contrast to bone scans with technetium-99m in progressing metastatic prostate cancer. Patients with histologically proven prostate adenocarcinoma and clinical evidence of disease progression as defined by a rising PSA and a detectable abnormality on a conventional imaging study, such as bone scan, CT, or MRI. Patients were considered castrate if testosterone levels were less than 50 nanograms/deciliter (ng/dL) in blood. Bone scan were performed at study initiation (30 days before to seven days after first treatment); FDG PET was performed in 43 patients before treatment initiation, and these 43 patients were further analyzed. Follow-up bone scans were performed three to six weeks after initiation of therapy. Images were interpreted by a radiologist and a nuclear medicine physician unaware of patients' specific findings (although they were aware of their progressive prostate cancer status). The authors found that in the 43 evaluable patients, the median time between bone scan and PET scan was 11.6 days with a maximum of 46 days. Bone scans indicated metastases in more patients (37/43, 86% of patients) than did FDG PET (31/43, 72% of patients) (p=0.01). In patients with negative bone scans, 1/6 had a metastatic lymph node lesion demonstrated on FDG PET. SUVmax on FDG PET scans did have some prognostic value for survival; in 22 patients whose metastases had an SUVmax ≤ 6.10, median survival was 32.6 months; in 21 other patients whose metastases had an SUVmax > 6.10, median survival was only 14.4 months (p = 0.002). The authors recognized some limitations of their study, for example the difficulty accurately sizing lesions in bone. They concluded that SUVmax is a prognostic indicator for prostate cancer metastatic to bone, even though FDG PET is able to detect osseous metastases in only 18-65% of patients based on previously published cases.

Prospective Case Series

Bannas P, Derlin T, Groth M, et al. Can 18F-FDG PET/CT be generally recommended in patients with differentiated thyroid carcinoma and elevated thyroglobulin levels but negative I-131 whole body scan? Ann Nucl Med 2012; 26: 77-85.

Based on a prospective case series of patients who had completed initial anticancer therapy with differentiated thyroid cancer, this article describes how the authors evaluated FDG PET/CT for recurrence of differentiated thyroid carcinoma (DTC) with elevated thyroglobulin (Tg). After total thyroidectomy and radioiodine ablation, patients were referred for a whole body scan using 131I tracer. If that scan was negative, and the patient's Tg was > two ng/mL, the patient was a candidate for an FDG PET/CT study to detect possible DTC recurrence. Results were verified by histology, ultrasound, or clinical follow-up. FDG PET/CT images were interpreted by two nuclear medicine physicians and two radiologists. Results of FDG PET/CT images were correlated with histology, other diagnostic studies, and clinical follow-up. The authors found the performance characteristics of FDG PET/CT to be as shown in the table below.

Table (adapted from Bannas 2012, Table 4)

Performance indicator	All patients	Patients with Tg > 10 ng/mL
Sensitivity	68%	70%
	60%	100%

Performance indicator	All patients	Patients with Tg > 10 ng/mL
Specificity		
Negative predictive value	27%	14%
Positive predictive value	89%	100%
Accuracy	67%	71.4%

The authors concluded that FDG PET/CT enables detection and localization of recurrences of DTC. They also noted that post-PET/CT findings, treatment changed in 17 (57%) of 30 patients.

Benz M, Evilevitch V, Allen-Auerbach MS, et al. Treatment monitoring by 18F-FDG PET/CT in patients with sarcomas: interobserver variability of quantitative parameters in treatment-induced changes in histopathologically responding and non-responding tumors. J Nucl. Med. 2008 Jul; 49(7): 1038-46.

In this prospective study of patients with high-grade soft-tissue sarcomas undergoing neoadjuvant chemotherapy (a companion paper to the Evilevitch study 2008(below)), the authors measured various quantitative parameters (e.g., SUVmean) from before and after FDG PET scans and evaluated their relative variability. Although some of these parameters can be automatically assigned by software, high variability of FDG uptake within the tumor caused frequent failure of the automatic thresholding algorithm, necessitating manual corrections that may have increased variability of calculated parameters related to SUV (see below). Patients were eligible if they had either biopsy-proven osteosarcoma or soft tissue sarcoma, were considered surgical candidates, and were scheduled to undergo preoperative chemotherapy or chemoradiotherapy. Patients underwent pre- and post-therapy FDG PET/CT scans, following study-specific scanning and patient preparation protocols. FDG PET images were analyzed by two independent observers unaware of the clinical data and histopathologic response, using the same workstations and software to co-register baseline and follow-up FDG PET/CT studies. Tissue subsequently removed at surgery was evaluated for tumor necrosis, with histologic response based on a finding of 10% or fewer viable tumor cells in resected tissue. The following parameters were calculated based on FDG PET/CT scan data: maximum standardized uptake value (SUVmax), peak SUV (SUVpeak), mean SUV in all pixels with SUV > 0% of SUVmax (SUVauto), mean SUV based on baseline FDG PET/CT study (SUVmean), and tissue background ratio comparing tumor-region SUVs with those on the contralateral normal soft tissue (TBR).

The authors found that in these 33 patients, eight had osteosarcomas, and 25 had soft tissue sarcomas. The mean age of the 16 male and 17 female patients was 47.1 years, ranging from 19 to 86 years. Among these patients, 27 (82% of) patients presented with sarcoma in an extremity; 28 (85% of) patients had primary disease. Tumor size ranged from 3.4-20.3 cm (before presurgical therapy) to 2.3 to 25.8 cm afterwards. The average histologic response of tumors was 65%, ranging from 9 to 99.9%. Based on histopathology and the response criterion above, ten patients were classified as responders; 23 were non-responders. The authors concluded that SUVmax and SUVpeak showed low variability and separated histologic responders from non-responders. The authors commented that intratumoral heterogeneity was high in sarcomas and suggested that additional research studies would be valuable.

Evilevitch V, Weber WA, Tap WD, et al. Reduction of glucose metabolic activity is more accurate than change in size at predicting histopathologic response to neoadjuvant therapy in high-grade soft-tissue sarcomas. Clin Cancer Res. 2008 Jan; 14(3): 715-20.

In this multi-center study of patients with operable soft-tissue sarcomas, the authors used a before and after design to assess whether change in glucose metabolism after neoadjuvant chemotherapy as measured by positron emission tomography with FDG PET allows for a more accurate evaluation of histopathologic response than change in tumor size. Relative changes in tumor FDG uptake and size from the baseline to the follow-up scan were calculated, and their accuracy for assessment of histopathologic response was compared by receiver operating characteristic curve analysis. Histopathologic response was defined as ≥ 95% tumor necrosis.

The authors found that in histopathologic responders (n = 8; 19%), reduction in tumor FDG uptake was significantly greater than in non-responders ($P < 0.001$), whereas no significant differences were found for tumor size ($P = 0.24$). The area under the receiver operating characteristic curve for metabolic changes was 0.93, but only 0.60 for size changes ($P = 0.004$). Using a 60% decrease in tumor FDG uptake as a threshold resulted in a sensitivity of 100% and a specificity of 71% for assessment of histopathologic response, whereas Response Evaluation Criteria in Solid Tumors showed a sensitivity of 25% and a specificity of 100%. The authors concluded that quantitative FDG PET was significantly more accurate than size-based criteria at assessing histopathologic response to neoadjuvant therapy. However, the authors noted that the quantitation of response in patients with liposarcoma is limited due to the low metabolic level of such tumors.

Feigen M, Lee ST, Lawford C, et al. Establishing locoregional control of malignant pleural mesothelioma using high -dose radiotherapy and FDG PET/CT scan correlation. J Med Imaging Rad Oncol. 2011; 55: 320-22.

In this series of patients with malignant pleural mesothelioma, the authors used FDG PET/CT to assess response of disease to high-dose palliative radiotherapy. Eligible patients were those with histologically confirmed mesothelioma of any subtype, limited to one hemithorax and with otherwise normal physiology, and not dependent on prior pleurectomy/decortication or other therapy. Patients underwent FDG PET/CT studies prior to radiotherapy in order to plan the target volume for radiotherapy, with followup studies at least three months after completing radiotherapy by either external beam or intensity-modulated radiotherapy. Patient imaging was performed using study-specific preparation and scanning protocols. All FDG PET scans for short or long-term follow-up, performed a median of 17 months after completion of radiotherapy, were compared with pre-treatment scans and SUVmax and total glycolytic volumes (TGVs) were calculated by software. The authors found that of the 14 patients eligible for the study, there were twelve males and two females, with median age of 62 years, ranging from 37 to 72 years. All had prior exposure to asbestos. Median survival of all patients from the time of diagnosis was 28 months, range 10-79 months. In ten of 14 patients, TGV decreased a median of 61% from baseline to initial follow-up FDG PET/CT scan. The authors acknowledged that in some patients, inflammation within the treated volume (associated with radiation pneumonitis) and the ten millimeter resolution limit of FDG PET studies were confounding factors in assessing either tumor volume for radiation treatment or potential failure of locoregional control.

Giovanella L, Ceriani L, DePalma D, et al. Relationship between serum thyroglobulin and FDG PET/CT in ^{131}I-negative differentiated thyroid carcinomas. Head Neck. 2012; 34: 626-31.

In patients with histological proven differentiated thyroid carcinoma (DTC) treated with total thyroidectomy and subsequent ^{131}Iablation, the authors wished to determine the ability of FDG PET/CT to detect recurrent DTC in patients with elevated thyroglobulin (Tg) levels but who are negative for recurrence on ^{131}I imaging. Follow-up FDG PET/CT studies were performed an average of 2.2 months after ^{131}I ablation. Scans were performed after a study-specific patient preparation protocol. Serum Tg was sampled just before the FDG PET/CT study, and patients were screened for anti-Tg antibodies to detect possible assay interference. Studies for recurrence were interpreted by two experienced nuclear medicine physicians who were unaware of other clinical or imaging results. The gold standard for comparison was a combination of follow-up information, including Tg levels and cytologic or histologic results, or other imaging modalities including MRI, CT, and ultrasound. The authors found that data from 42 patients were available for analysis. Average patient age and exact numbers of male and female patients tested were not available from the information provided. The following table shows the authors' calculations of diagnostic performance indicators:

Table (adapted from Giovanella 2012, p. 629)

Performance Index	Percent (%)
Sensitivity	93
Specificity	84
	93

Performance Index	Percent (%)
Negative predictive value	
Positive predictive value	84
Accuracy	90

In the subset of patients with Tg levels of 4.6 ng/mL or greater, sensitivity increased from 93-96%). However, three of 27 patients with true positive FDG PET/CT scans had Tg levels less than 4.6 ng/mL. The authors concluded that use of a Tg cutoff level of 10 ng/mL might decrease sensitivity of FDG PET/CT studies in such patients.

Holdsworth CN, Badawi RD, Manola JB, et al. CT and PET: early prognostic indicators of response to imatinib mesylate in patients with GIST. Am J Roentgenol. 2007 Dec; 189 (6):W324-30.

In this retrospective re-analysis of patient data from a Phase II trial of imatinib mesylate therapy for patients with advanced GIST at two institutions, the authors reported results of a pilot study showing that FDG PET SUVmax results indicated response (as time to treatment failure (TTF)). Patients underwent FDG PET prior to imatinib treatment (baseline) and 21-40 days after treatment initiation. For each patient, SUVmax was calculated for the lesion with the most intense uptake at baseline and was subsequently calculated for the same lesion on follow-up scans. Percent change in SUVmax at one month was also calculated for each patient. Most patients also underwent CT scans before treatment and 21-40 days after treatment. Investigators used study-specific preparation and scanning protocols. The outcome measure, time-to-treatment failure, was defined as the time from the first dose of imatinib mesylate to the earliest occurrence of disease progression, death or discontinuation from the trial for any medical reason. Recursion methods were used to find the optimal SUVmax cutpoint for TTF. The authors found that participating patients included 40 men (with mean age 54 years, ranging from 25-80 years) and 23 women (mean age 56 years, ranging from 19-84 years). Twenty-seven patients were treated per prior study protocol with an initial imatinib dose of 400 mg per day; 36 patients received 600 mg per day. Using several PET-related criteria to separate tumor response groups, the authors showed the FDG PET related response metrics were significant predictors of actual TTF:

Table (Adapted from Table 1, Holdsworth 2007)

Metric	Threshold	TTF, months	Significance
	> 3.4 vs. ≤ 3.4	2.9 vs. 26.3	$p < 0.0001$

Metric	Threshold	TTF, months	Significance
PET SUVmax			
40% or greater reduction in PET SUVmax	N/A	2.9 vs. 26.3	$p < 0.0001$
25% reduction in SUVmax	N/A	5.1 vs. 23.0	$p < 0.004$
Standard SUVmax	> 2.5 vs. < 2.5	5.7 vs. 24.5	$p < 0.04$

The authors concluded that current FDG PET-related response metrics for GIST therapy with imatinib mesylate should be re-analyzed and improved, given that prior criteria for tumor response might not be applicable to newer targeted therapies such as imatinib. They suggested additional studies would be appropriate.

Nahmias C and Wahl LM. Reproducibility of SUV measurements determined by FDG PET in malignant tumors. J. Nucl. Med. 2008 November; 49(11): 1804-8.

This clinical study attempted to estimate the reproducibility and confidence levels of metabolic activity in malignant tumors using standardized uptake values (SUVs), as determined by FDG PET on two occasions no more than five days apart. Twenty six patients were studied, including ten women and 16 men, with a mean age of 61 years (range 25-72 years). Nine patients had esophageal cancer; six had metastatic breast cancer; three had esophageal cancer; and the other eight had cancers in various other locations. None of the patients was undergoing chemotherapy at the time of the study. Before and during each of the two PET examinations, patients fasted on a standard protocol, received a standard dose of FDG, and were scanned on a single type of PET scanner from chin to pelvis with PET data acquired for the same time interval. A CT scan of the same area was performed with standard settings. For calculation of SUVmax and SUV_{mean}, ROIs were determined using PET images from the first study to define regions of interest and, if metastases were present, from the metabolically most active lesion. Resolution of reconstructed PET images was approximately 8 mm, and regions of interest (ROIs) varied between nine and 17 mm. The authors found that patient weights and plasma glucose concentrations between the studies were not significantly different from zero (in kg and mg/dL respectively). The mean FDG uptake period was 94 +/- 9 minutes; the mean difference between FDG uptake periods for the 26 subjects was 0 +/- 8 minutes (range, -26 to 18 minutes). SUV_{mean} for the first and second PET scans in the chosen regions of interest ranged from 1.49 to 17.48, and SUVmax ranged from 2.99 to 24.09. The Pearson correlation coefficient *r* between SUV_{mean} determined in the two scans was 0.99 ($n = 26$; $p < 0.0001$, 95% CI: 0.99-1.00). In addition the mean difference in SUVmax between the first and second PET scans was not significantly different from zero (mean difference -0.05; 95% CI: -2.32 to 2.23). The authors concluded that serial measurement of FDG PET SUVmax and SUV_{mean} can be performed reproducibly. The authors mentioned that most commercial PET scanners are able to perform the SUVmax and SUV_{mean} calculations if the injected dose and the patient weight are entered.

Ozkan E, Soydal C, Araz M, et al. The additive clinical value of FDG PET/CT in defining the recurrence of disease in patients with differentiated thyroid cancer who have isolated increased antithyroglobulin antibody levels. Clin Nucl Med. 2012 Aug; 37: 755-8.

In this retrospective analysis of patients with differentiated thyroid carcinoma (DTC) who underwent FDG PET/CT examination, the authors investigated the clinical value of FDG PET/CT in detecting the recurrence of disease with negative ^{131}I whole-body scans, undetectable thyroglobulin (Tg) and increased anti-Tg levels. Patients with anti-Tg associated with lymphocytic thyroiditis were excluded from the study. Whole-body images were interpreted by consensus of two experienced nuclear medicine physicians. A combination of clinical follow-up and histologic results was used as the reference standard. The authors found that 27 women and four men, with average age of 50.2 years, qualified for the study. Average time from thyroidectomy to FDG PET/CT scan was 30 months. All these patients had undetectable serum Tg and increased anti-Tg levels. The authors calculated the performance characteristics of FDG PET/CT for recurrent DTC detection were as follows:

Table (adapted from Ozkan 2012, p. 757)

Performance Index	Percent (%)
Sensitivity	75
Specificity	76

Performance Index	Percent (%)
Negative predictive value	86
Positive predictive value	75
Accuracy	80

The authors concluded that FDG PET/CT may be useful in patients with suspected DTC recurrence, whose Tg levels are undetectable due to anti-Tg antibodies.

Rubello D, Rampin L, Nanni C, et al. The role of FDG PET/CT in detecting metastatic deposits of recurrent medullary thyroid carcinoma: a prospective study. Eur J Surg Oncol. 2008; 34: 581-6.

Based on a series of patients with histologically confirmed, previously treated medullary thyroid carcinoma (MTC), the authors used FDG PET/CT and other imaging modalities to determine the optimal mode of detecting recurrent disease in this prospective study. Serum calcitonin and CEA levels were assessed at the time of referral to this study, along with high-resolution neck ultrasound (US), FDG PET/CT, ^{111}In pentetreotide scintigraphy, and whole body CT. Additional follow-up included periodic physical examination, calcitonin and CEA levels, and imaging as need for clinical management. FDG PET/CT was guided by study-specific patient preparation and scanning protocols. Interpretation of images was done visually by two experienced nuclear medicine physicians blinded to clinical information. SUV levels were used to highlight foci of greatest FDG accumulation. Final diagnoses were made by cytopathology of fine needle aspirates, or by histopathology. The authors found that of 19 patients referred to the study, eleven were female and eight were male, and that ages of patients ranged from 34 to 73 years with a mean age of 53.4 years. All had undergone total thyroidectomy and lymphadenectomy. Some had also been undergone chemotherapy or beam radiotherapy or radiopharmaceutical therapy. Time from first treatment to study entry ranged from 24 months to 13 years. FDG PET/CT detected metastases in 15/19 patients, with eight metastases in neck lymph nodes, five in head lymph nodes, and five in mediastinal lymph nodes, and two in both neck or mediastinal lymph nodes and in bone. In contrast, ^{111}In pentetreotide scanning detected eight patients with metastases (five with neck lymph node metastases, three with both neck and mediastinal metastases). CT detected metastases in eleven patients, and US detected neck metastases in six lymph nodes. In four of nineteen study patients, no imaging method detected metastases. No false positive findings of metastases were found in any patient based on FDG PET/CT, CT, or ^{111}In pentetreotide scanning, but US studies on three patients were false positive due to reactive enlargement of lymph nodes negative for malignancy by fine needle aspiration. The authors noted that calcitonin levels in the range 590 – 1350 pg/mL were more likely to reflect FDG PET/CT positive cases. It was also noted that FDG PET/CT findings of multiple metastases in the neck and mediastinum contributed to planning a subsequent re-excision in three patients. The authors concluded that FDG PET/CT is superior to other imaging methods for detecting and localizing recurrence of MTC. They acknowledged that the relative small size of the patient series (n = 19) was a limitation of their study.

Santra A, Kumar R, Sharma P, et al. F-18 FDG PET-CT in patients with recurrent glioma: comparison with contrast enhanced MRI. Eur J Radiol. 2012; 81: 508-13.

In this prospective series, the authors compared the efficacies of FDG PET-CT and contrast-enhanced MRI in detecting recurrent gliomas. 90 patients with histologically proven glioma suspected on clinical grounds of recurrent were recruited for the study between August 2006 and February 2008. Patients with other types of primary brain tumors or with metastases to brain were excluded. Studies were performed on an integrated PET-CT scanner in a single institution. All patients fasted for at least four hours preceding the FDG PET-CT scan and had glucose levels less than 140 mg/dL. 45-60 minutes after intravenous injection of a 370 MBq (10 mCi) dose, FDG PET-CT scans were performed. MRI images were acquired on a clinical MRI imaging unit, after IV administration of gadopentetate dimeglumine (Gd-DTPA) at a standard dose for contrast. Images were interpreted by experienced physicians, blinded to the clinical and structural findings. The comparison reference standard was a combination of biopsy (when available), repeat imaging, or clinical follow-up as available. The authors found that the patients' mean age was 36.8 years, ranging from 12 – 68 years. Sixty-six men and 24 women were participants. Tumor histologies included glioblastoma multiforme, astrocytoma, oligodendroglioma, or mixed gliomas. Surgery with radio- and/or chemotherapy had been the most frequent types of primary therapy in these patients. After a follow-up period of at least six months, the table shows how many participants were positive for recurrent glioma by either PET-CT scan, MRI with contrast, or by clinical follow-up:

Table (adapted from Santra 2012, pp. 508-9)

Mode of recurrence detection:	Patients positive for recurrence:
Clinical follow-up, repeat imaging, or biopsy	59/90 (66%)
PET-CT	42/90 (47%)
MRI with contrast	80/90 (89%)

The authors concluded that overall, MRI with contrast had high sensitivity (95%) but poor specificity (23%) for detection of recurrent gliomas. FDG PET-CT in contrast had lower sensitivity (70%) but higher specificity (97%). The authors noted that FDG PET-CT was able to correctly delineate mixed lesions (of recurrent tumor and radiation necrosis) in eleven patients. The authors also noted that many primary brain gliomas are similar in glucose metabolism to adjacent gray matter, increasing the difficulty of distinguishing some gliomas from normal brain tissue. The authors suggested that the increased false-negative rate of FDG PET-CT make it less attractive as a primary imaging approach for detecting recurrences, and that it be used instead to characterize any abnormal lesion found on MRI. The authors commented that additional research might be of value. The authors also noted (as a study limitation) that only five of these 90 cases had confirmation of recurrence based on histologic evidence.

Seo JH, Lee SW, Ahn B-C, Lee J. Recurrence detection in differentiated thyroid cancer patients with elevated serum level of antithyroglobulin antibody: special emphasis on using FDG PET/CT. Clin Endocrinol 2010; 72: 558-63.

In this prospective series of patients with prior total or near-total thyroidectomy and high-dose radioiodine ablation, the authors investigated the use of FDG PET/CT in patients with elevated antibody to thyroglobulin (anti -Tg). The reference standard for recurrent differentiated thyroid cancer (DTC) was a combination of SUV of three or better; or follow-up imaging or histologic or cytologic confirmation; or clinical follow-up 6-12 months later. The authors found that in detecting recurrence of DTC among patients with anti-Tg, PET/CT showed sensitivity, specificity, and accuracy of 75.6%, 87%, and 85.6% respectively. They concluded that in patients with anti-Tg antibodies, FDG PET/CT was clinically useful, but suggested that additional studies were needed.

Sperti C, Pasquali C, Bissoli S, et al. Tumor relapse after pancreatic cancer resection is detected earlier by 18-FDG PET than by CT. J. Gastrointest Surg. 2010; 14: 131-40.

In this prospective study, the authors evaluated the impact of FDG PET in the diagnosis of recurrent pancreatic cancer. The study focused on 138 patients following resection of the pancreas for adenocarcinoma between January 1997 and July 2008. Of these, 66 patients were excluded as: lost to follow-up; due to death after surgery; or due to not having an FDG PET performed. Standardized follow-up on the remaining 72 included physical examination, laboratory studies including tumor markers, and imaging studies including CT and MRI on a standardized schedule. Of these 72 patients, pancreatic tumor relapse was detected by CT in 35 (49%) and by FDG PET in 61 (85%). FDG PET influenced treatment strategies in 32/72 patients (44.4%). Disease-free survival was similar in both groups. The authors concluded that FDG PET detected tumor relapse earlier, but that an earlier diagnosis of relapse did not affect survival due to the lack of effective therapy.

Tan H, Chen L, Guan Y, et al. Comparison of MRI, FDG, and ^{11}C methionine PET/CT for their potentials in differentiating brain tumor recurrence from brain tumor necrosis following radiotherapy. Clin Nucl Med 2011 Nov; 36(11): 978-81.

In this retrospective review of patients with primary and secondary (metastatic) brain tumors following radiotherapy, the authors compared the capacity of FDG PET to recognize recurrent tumor with radiation injury with those of several other imaging technologies, including ^{11}C methionine (MET) PET/CT and MRI. PET/CT scans were performed after a standardized patient preparation protocol. The reference standard was either pathologic verification or clinical follow-up. The authors found that among 55 subjects, 45 were male, and ten were female. Ages ranged from 17-79 years with a mean age of 57 years. Primary histologic diagnoses included: gliomas in 37 subjects; metastatic lesions in 15 subjects; and unusual primary brain tumors in three subjects (neuroblastoma, CNS lymphoma, and germinoma). All patients were suspected of recurrences or of radiation injury following radiotherapy. Each subject was followed up for at least eleven months. The following table illustrates how well the selected imaging studies performed.

Table (Adapted from Tan 2011, Table 1)

Diagnosis	n	MRI Sensitivity	FDG PET/CT Sensitivity	MET PET/CT Sensitivity
Recurrence	39	87.2%	76.9%	92.3%

The authors concluded that MET PET/CT offers an effective means to distinguish brain tumor recurrences from radiation injury. However, due to some false negatives with MET PET/CT, it should be combined with clinical assessment for optimal use.

Topkan E, Parlak C, Kotek A, et al. Predictive value of metabolic FDG PET response on outcomes in patients with locally advanced pancreatic carcinoma treated with definitive concurrent chemoradiotherapy. BioMedCentral Gastroenterol. 2011; 11: 123, 1-9.

In this prospective study of patients with unresectable, non-metastatic pancreatic cancer with histologic proof of malignancy, the authors evaluated the predictive utility of post-treatment FDG PET results. The extent of disease in enrolled patients was determined by CT, MRI, or MR-cholangiopancreaticography (MRCP), with restaging of patients for radiotherapy with FDG PET/CT within ten days of treatment. Imaging studies were guided by institution-specific protocols for patient preparation and scanning. Radiotherapy protocols observed maximum dosage limits for specific internal organs or structures (e.g., spinal cord). Patients received 5-fluorouracil (5-FU) during the RT course as a radiosensitizer. Treatment response and follow-up were based on FDG PET/CT at twelve weeks, in addition to a number of other laboratory and imaging tests. Predictive utility of FDG PET/CT on clinical outcomes was studied based on differences in SUVmax from pre- to post-treatment scans. Patients were grouped by SUVmax differences into two groups separated by the median SUVmax difference, and then compared to local/regional progression free survival (LRPFS), progression-free survival (PFS), and overall survival (OS). Statistical analysis of survival information and of the relation of SUVmax differences to known prognostic values (such as age, gender, and nodal involvement). The authors found that 44 patients were enrolled, and, after twelve were excluded due to distant metastases and referred for systemic therapy, 32 patients remained eligible for analysis. Median SUVmax difference was -63.7%. The authors found a statistically significant difference in all survival measures (OS (p = 0.009), PFS (p = 0.005), and LRPFS (p = 0.02)) for patients with an SUVmax reduction greater than 63.7%. Corresponding median survival times for the patient group with greater versus lesser SUVmax changes (compared to 63.7% decrease) are shown in the following table:

Table (adapted from Topkan 2011)

Survival Measure:	Median survival time, patients with greater SUVmax changes (months, with 95% CIs)	Median survival time, patients with lesser SUVmax changes (months, with 95% CIs)
PFS	8.4 (5.5 - 11.3)	3.8 (1.8 – 6.7)
LRPFS	12.3 (3.1 – 21.5)	6.9 (1.8 – 12.0)
OS	17.0 (14.5 – 19.4)	9.8 (7.2 – 12.4)

The authors noted that, in addition to its ability in pre-treatment radiotherapy planning, FDG PET/CT's ability to indicate improved survival by the difference in SUVmax from pre- to post-treatment images contributes its value in pancreatic cancer management. The authors acknowledged the small sample size of the study as a limitation, and suggested that larger studies would be useful.

Retrospective case series

Alousi AM, Saliba RM, Okoroji GJ, et al. Disease staging with positron emission tomography or gallium scanning and use of rituximab predict outcome for patients with diffuse large B-cell lymphoma treated with autologous stem cell transplantation. 2008. Brit J Haematol 142:786-792.

In this retrospective study, the authors evaluated the influence of rituximab on progression-free survival (PFS) in patients with diffuse large B-cell lymphoma (DLBCL), based on FDG PET scans and gallium scan ('PET/G') status before autologous stem cell transplant (ASCT). They included for review all patients with chemosensitive DLBCL who underwent ASCT in research protocols at one institution. The authors found that the median age of 174 patients reviewed was 47 years (range, 16-75 years) and included 101 men and 73 women. Except for 9/174 patients who had no scans, the patients had nearly equal numbers of FDG PET scans and gallium scans, because prior to December 2002, ^{67}Ga scans had been used at that institution. Based on either type of scan, 29/174 patients had positive scan results for lymphoma, while 136/174 had negative scan results. Most patients had undergone prior therapy of some type, and some had achieved complete remission. Outcomes after ASCT in these patients, as measured by PFS rate (the cumulative proportion surviving free of progression) at six years, was best (74%) among those with negative scan status before ASCT and whose therapy included rituximab; while PFS rate was worst (10%) among patients with positive scan status before ASCT and whose therapy did not include rituximab. The authors considered the inability of study size to enable a comparison of predictive value of gallium vs. FDG PET scans to be a limitation. The authors concluded that evidence of disease status by PET or gallium scan prior to ASCT was associated with progression free survival rate.

Mini A, Xiao L, Allen PK, et al. Celiac node failure patterns after definitive chemoradiation for esophageal cancer in the modern era. 2012. Int J Radiation Oncol Biol Phys 83:231-239.

In this study, the authors described a retrospective, single-center investigation to assess whether pre- and post-treatment FDG PET SUV changes predict local failure (metastases) to the celiac lymph nodes as a way to assess tumor response. The authors reviewed radiation treatment volumes for 131 patients who underwent definitive chemoradiation treatment (CRT) for esophageal cancer. Patients with celiac node involvement at baseline were excluded. The authors found that the median patient age was 71 years, ranging from 30 to 83 years. 113/131 study participants were males. Median followup time was 52.6 months, with a 95% CI of 46.1 – 56.7 months. In 60/131 patients in whom the radiation treatment volume did not include the celiac lymph nodes, six had celiac node failure. Of 71/131 patients whose celiac lymph nodes were within the radiation treatment volume, five patients had celiac node failure. The inclusion of the celiac lymph nodes in the radiation treatment volume was not associated in a statistically significant way with celiac lymph node failure. In multivariate analysis, a pre- to post-treatment change in PET SUV of 52% or more, in patients who had failure in the clinical target volume, were significantly associated with risk of celiac lymph node failure. Of those 60 patients whose radiation tumor volumes did not include the celiac lymph nodes, the six patients with celiac lymph node failure had a worse median overall survival time compared with the 54 who did not fail (median overall survival time: 16.5 vs. 31.5 months, $p = 0.041$). The authors noted that staging techniques improved greatly during the seven year period covered by this retrospective study.

Choi JW, Lee JH, Baek JH, et al. Diagnostic accuracy of ultrasound and FDG PET or PET/CT for patients with suspected recurrent papillary thyroid carcinoma. Ultrasound in Med. & Biol. 2010; 36(10): 1608-15.

In this retrospective consecutive case series of patients with papillary thyroid carcinoma who had undergone total thyroidectomy and radioiodine ablation, the authors compared the diagnostic accuracy of ultrasound to that of FDG PET for the diagnosis of recurrent disease. Eligibility for study selection included clinical suspicion of recurrent disease based on serum thyroglobulin levels or clinical examination. Ultrasound studies were done by physicians aware of the clinical diagnosis. FDG PET studies were guided by institutional protocols. Recurrence was considered proven based on results of fine needle aspirate, excisional biopsy; follow-up imaging studies of any type, including ^{131}I whole body scan; or a serologic test. The authors found that 76 patients were eligible for the study, including 18 men and 58 women. Their average age was 45.4 years, ranging from 17 to 77 years. Based on their definition of recurrence, 53/76 patients recurred. The following table compares the performance characteristics of each test for recurrent disease:

Table (adapted from Choi 2010, Table 3)

Performance Index	Ultrasound	FDG PET
Sensitivity	72%	57%
Specificity	70%	52%
Accuracy	71%	55%
Positive predictive value	84%	73%
Negative predictive value	52%	34%

The authors calculated that there were no statistically significant differences in sensitivity, specificity or accuracy. The authors also noted that either method of detecting recurrence led to treatment management changes in 30 - 40% of patients. In two of 76 cases, FDG PET was of value because distant metastases were detected. The authors concluded that neck ultrasound had higher accuracy than FDG PET in detecting local recurrences in patients with suspected recurrent papillary thyroid carcinoma.

Conry BG, Papathanasiou ND, Prakash V, et al. Comparison of ^{68}Ga-DOTATATE and FDG PET/CT in the detection of recurrent medullary thyroid carcinoma. Eur J Nucl Med Mol Imaging. 2010; 37: 49-57.

In this retrospective study, the authors compared the gallium-based PET radiopharmaceutical ^{68}Ga-DOTATATE (a somatostatin analogue) with FDG PET for detecting and assessing extent of recurrent medullary thyroid cancer (MTC). Verification of the lesions detected by either tracer was achieved by histopathologic analysis, further imaging studies, and clinical follow-up. The authors found that in 18 patients previously operated on for MTC and with either raised calcitonin levels or imaging evidence of recurrence, imaging for both ^{68}Ga-DOTATATE and FDG had been done within no more than four weeks, six patients were 60 years of age or older, and five of these six patients were men. Recurrent MTC was detected in 13 (72.2%) of 18 patients by ^{68}Ga-DOTATATE PET/CT and in 14 (77.8%) of 18 patients by FDG PET/CT. However, in ten patients the two radiotracers provided discordant images of the recurrent disease based on visual review of lesions and/or regions involved. The authors suggested that ^{68}Ga-DOTATATE PET/CT may be a useful complementary tool with FDG PET/CT for detection of MTC recurrence.

Dahele M, Ung YC, Ehrlich L, et al. FDG PET-CT for suspected recurrent papillary thyroid cancer: early experience at Sunnybrook Health Sciences Center. J Otolaryngol. – Head Neck Surg. 2008; 37: 712-7.

Based on a retrospectively studied series of patients with prior total or near-total thyroidectomy, some of whom had also received radioiodine ablation, these authors reported on their experience with FDG PET for detecting recurrent papillary thyroid cancer (PTC). The authors found that the 14 females and two males in the study had an average age of 47 years, ranging from 22 to 72 years. Median time from initial thyroid surgery was ten years (range: three – 17 years). Three (18%) of 17 FDG PET scans in these patients were reported as suspicious for recurrent PTC in the neck, and these were subsequently confirmed on histopathology. The authors commented that this preliminary report of one institution's experience might contribute to the use of FDG PET in patients with PTC.

Jacene HA, Leboulleux S, Baba S, et al. Assessment of interobserver reproducibility in quantitative FDG PET/CT measurements of tumor response to therapy. J. Nucl. Med. 2009 Nov; 50(11): 1760-9.

This retrospective clinical study compared the reproducibility of SUVs and CT size measurements, and changes in those measurements, in breast and lung cancers before and after therapy. A list of patients with both pre- and an early post-treatment FDG PET scans were retrospectively compiled from April 2003 to April 2005. Patients underwent FDG PET scans after a standardized fasting period and check that blood glucose was less than 200 mg/dL. Oral (not intravenous) contrast was administered for the CT portion of the study. After an approximately 60 minute uptake period, scanning was performed on the same type of integrated PET/CT scanner for all patients with standard scan parameters. Maximum SUVs and CT size measurements were determined for each selected tumor (based on the pre-treatment images) independently on pre- and post-treatment scans by eight different readers (four for PET, four for CT). Percentage changes between pre- and post-treatment scans, interobserver reproducibility by intraclass correlation coefficients (ICCs) and estimates of variance were calculated. PET images were reviewed on a single type of workstation, and PET, CT, and fused PET/CT images were reviewed on a single split screen. Readers were asked to identify the SUVmax on each tumor from both pre- and post-treatment scans using the SUV tools on the workstation. CT images were reviewed using CT image software from a single manufacturer to measure the long and perpendicular axis of each tumor. Tumor volume was based on the product of these two measurements. Response assessments were based on criteria used in RECIST and WHO clinical trials. Results of measurements from at least three readers were required to include a case in the statistical analysis.

The authors found that 25 patients, six men and 19 women, had a mean age of 51 years. 16 had primary breast cancer, nine had primary lung cancer. Treatment modalities between the pre- and post-treatment PET/CT scans included chemotherapy (n = 21), hormonal therapy alone (n = 1) and chemotherapy with either hormonal, biologic, or radiotherapy (n = 3). 52 tumors (up to three per patient) were identified for review. The median tumor size was 22 mm (range 10-58 mm) by 15 mm (range 7-41 mm). The mean time between pre-treatment and post-treatment FDG PET/CT scans was 52 days (range: 8-175 days). Factors known to affect SUV such as serum glucose, body weight, injected dose activity, and FDG uptake time, were not significantly different among the patients. On average, SUVmax was significantly higher on the pre- than on the post-treatment scans (9.6 +/- 6.3 vs. 4.6 +/- 4.0, $p < 0.001$). The average 2-dimensional CT tumor size was also significantly higher on the pre - than on the post-treatment scans (541.8 +/- 607.8 sq. mm. pre- vs. 410.7 +/- 637.3 sq. mm. post-treatment, $p < 0.009$). The average percent decline in SUVmax was 45% +/- 35%, which exceeded the 1- and 2-dimensional declines in CT size (20% +/- 33%, $p < .001$ and 24% +/- 56%, $p = 0.003$). There was a very high degree of reproducibility for percentage decline in SUVmax among the four PET readers, with an estimated variance (ICC) or 0.94 (95% CI, .90 - .96; precision +/- 3%). The CV was also lower for SUVmax than for CT 1- and 2- dimensional measurements of tumor size, in both pre- and post-treatment studies. Reproducibility was found to be greater for larger tumors or those with higher SUVmax measurements. The authors concluded that the reproducibility in assessing FDG PET SUVmax values was greater than in assessing CT 1- or 2-dimensional extent, for pre- and post-treatment FDG PET/CT scans.

The authors commented that some readers may have had difficulty with measurement of tumor characteristics if multiple tumors were in close proximity, and that at least one reader measured a different tumor lesion than the other three. The authors concluded that percentage change in SUVmax is a highly reproducible measurement of tumor response pre- and post- cancer treatment, especially in comparison to estimates of percentage change in tumor volume based on 2-dimensional measurements of CT images. They also suggested that automated tools for image analysis might improve interobserver reproducibility.

Jadvar H, Quan V, Henderson RW and Conti PS. [F-18]-Fluorodeoxyglucose PET and PET/CT in diagnostic imaging evaluation of locally recurrent and metastatic bladder transitional cell carcinoma. Int J Clin Oncol. 2008 Feb; 13(1): 42-7.

In this retrospective cohort study of patients with treated urinary bladder cancer, the authors assessed the diagnostic utility of FDG PET or FDG PET/CT in the evaluation of recurrent and metastatic disease. Thirty-five patients with histologically confirmed transitional cell carcinoma of the bladder were referred to the authors' FDG PET imaging center during a six year period from 2000 – 2006. Prior treatment included cystectomy with urinary diversion in all patients, with subsequent chemotherapy in 13 patients, chemoradiation therapy in eleven patients, and no additional therapy in eleven patients. Diagnostic validation was by biopsy in one patient and by clinical and radiological follow-up for up to five years in the remaining patients. Diabetes mellitus was not present in any patient. Investigators followed a standard routine for patient preparation and FDG injection; all patients had plasma glucose levels below 120 mg/dL. The study included 25 men and ten women, with an age range of 39 -86 years. Both FDG PET and CT studies were true positive in 19 patients and true negative in twelve patients, while in four patients, FDG PET and CT results were discordant. The clinical management of 6/35 patients (17%) was changed due to FDG PET and CT combined results. The authors commented that "(w)hether such a change in short-term clinical management resulted in a long-term benefit in a cost-effective manner could not be addressed by our study." The authors also commented on the need for prospective studies in larger patient cohorts to clarify the exact role of FDG PET in clinical decision-making and in affecting long-term outcomes.

Na SJ, Yoo IR, O JH, et al. Diagnostic accuracy of FDG PET/CT in DTC patients with elevated Tg and negative WBI: evaluation by Tg level. Ann Nucl Med. 2012; 26: 26-34.

The authors assessed the diagnostic accuracy of FDG PET, based on a retrospective review of FDG PET/CT images of patients with histologically proven, previously treated DTC with either elevated Tg levels or anti-Tg antibodies and with negative WBI scans. Studies were guided by institutional patient preparation and scanning protocols and interpreted by two experienced nuclear medicine physicians independently. FDG PET was considered positive based on visual interpretation, although SUVmax values were recorded. Recurrence was indicated by histopathology, persistent imaging abnormalities on US, CT, MRI, or abnormal follow-up Tg levels or anti-Tg levels. Performance characteristics were calculated at several different Tg levels. The authors found that 68 FDG PET images were available for review from 60 patients, 41 women and 19 men, with mean age 49 years, ranging from 26-75 years. All patients had undergone total thyroidectomy and high-dose radioiodine ^{131}I ablation. In 65 of 68 instances, Tg levels exceeded 2.0 ng/mL, ranging from 2.04 to 1015.65 ng/mL. Overall association of FDG PET results and evidence of recurrence or metastasis is shown in the following table.

Table (adapted from Na 2012, Table 3)

	Recurrence or metastasis by other tests		
FDG PET imaging	**Positive**	**Negative**	**Total**
Positive	43	2	45
Negative	19	4	23
Total	62	6	68

The authors also calculated the specificity of FDG PET based on Tg levels, and found generally that sensitivity increased with higher Tg levels, going from 29% at Tg levels of 2-5 ng/mL, to 86% at Tg levels of 20 ng/mL or more. They suggested that FDG PET was most helpful for detecting recurrent DTC at Tg levels of 5 ng/mL or nore. They noted that future studies might examine the potentially complementary roles of ultrasound (US) and FDG PET for detecting recurrences. The authors also commented that the potential for elevated Tg levels due to other causes detracts from their use in detecting recurrence.

Ozkan E, Soydal C, Kucuk ON, et al. Impact of ^{18}F-FDG PET/CT for detecting recurrence of medullary thyroid carcinoma. Nucl. Med. Commun. 2011; 32: 1162-8.

In this retrospective study of 33 patients with elevated calcitonin levels, undergoing FDG PET/C for restaging of disease after total or near-total thyroidectomy, the authors studied the its value in detecting recurrent MTC. Scans were performed following a study-specific protocol, and images were interpreted by two experienced nuclear medicine physicians. True positive FDG PET/CT findings of recurrence were histologically confirmed by fine-needle aspiration or on re-operation. The authors found that all patients had elevated calcitonin levels. Among 33 patients, nine were men and 24 were women. The mean age of all patients was 50.3 years of age. The authors calculated sensitivity and specificity of FDG PET testing for recurrence as 93% and 68%, respectively. For the subgroup of patients with calcitonin levels of 150 pg/mL or greater, the sensitivity and specificity of FDG PET were 90% and 71%, respectively. The authors noted that recurrent disease of only a millimeter in size would probably not be detected by FDG PET, and suggested that additional studies would be valuable.

Park J-Y, Kim EN, Kim D-Y, et al. Role of PET or PET/CT in the post-therapy surveillance of uterine sarcoma. Gynecol Oncol. 2008; 109: 255-62.

This retrospective study of 36 patients with treated uterine sarcoma who underwent FDG PET or FDG PET/CT in post-therapy surveillance was conducted in order to evaluate the clinical accuracy and impact of these diagnostic studies. The authors studied medical records, histopathologic and diagnostic imaging studies and follow-up of 36 women with histologically proven uterine sarcoma and with surgical therapy with or without adjuvant therapy between August 1999 and November 2006 at one medical center. Studies were done following a standard protocol for patient preparation, with scanning from the skull base to the upper thighs. All FDG PET or PET/CT images were interpreted by a single experienced nuclear medicine physician who was aware of the patient's clinical history and prior imaging results. Sites of increased uptake that could not be interpreted as physiologic uptake (e.g., the brain and urinary bladder) or due to known benign processes were considered malignant; sites whose significance was unclear were considered equivocal. Histopathology or clinical follow-up information after at least six months was used as reference standards.

The median age of the 36 patients was 48 years of age, ranging from 30 – 61 years. Histologically, the uterine sarcomas included low and high grade endometrial stromal sarcomas, leiomyosarcomas, and malignant mixed müllerian tumors. Tumor staging included: 23/36 patients were FIGO stage I; 2/36 were FIGO stage II; 9/36 were FIGO stage III; 2/36 were FIGO stage IV. As part of post-therapy surveillance, thirty scans (8 PET, 22 ET/CT) were performed due to suspected disease recurrence; 18 scans (4 PET and 14 PET/CT) were performed in asymptomatic patients. Twenty-seven of 36 patients underwent one scan each; seven underwent two scans; and two other patients underwent three and four scans. Median time after initial therapy to FDG PET or PET/CT scan was eleven months (range, 1-60 months) and median follow-up time was twelve months (range, 6-58 months). The authors calculated that, for all patients:

Performance Index	Percent (%)
Sensitivity	91
Specificity	96
Negative predictive value	93
Positive predictive value	95
Accuracy	94

Among asymptomatic patients, the authors calculated that:

Performance Index	Percent (%)
Sensitivity	87.5
Specificity	95.5

Performance Index	Percent (%)
Accuracy	93.3
Positive predictive value	87.5
Negative predictive value	95.5

Among patients with suspected disease recurrence, the authors calculated that:

Performance Index	Percent (%)
Sensitivity	92.9
Specificity	100
Accuracy	94.4
Positive predictive value	100
Negative predictive value	80

The authors found that these results altered patient management in twelve of 36 (33%) patients; previously unplanned treatment was started in eight patients, and four patients avoided a planned treatment. FDG PET or FDG PET/CT also contributed to surgical planning by confirming isolated recurrences. The authors concluded that FDG PET or FDG PET/CT is a sensitive post-therapy surveillance modality with impact on patient management.

Rakheja R, Makis W, Skamene S, et al. Correlating metabolic activity on FDG PET/CT with histopathologic characteristics of osseous and soft-tissue sarcomas: a retrospective review of 136 patients. Am J Roentgenol. 2012; 198: 1409-16.

In a consecutive case series, identified retrospectively at one institution, the authors evaluated the relationship of SUVmax from FDG PET/CT images of recurrent soft-tissue or osseous sarcoma with histologic features from final pathology reports. During a specific four-year period, a list of patients was compiled from imaging databases, and then was used to search for corresponding pathology reports on tumor specimens. FDG PET/CT studies were guided by institution-specific protocols. FDG PET/CT images, and especially determinations of SUVmax, were reviewed by multiple physicians. Tumor histopathology reports use international standard definitions for histologic features, tumor grading, and classification. The issuing pathologists were unaware of the FDG PET/CT information. The authors found histopathology reports on resected or biopsied tumors from 136 patients imaged during the study time period. The 136 patients ranged in age from 15 to 90 years of age, with a median age of 50 years. Of the 136 sarcomas found in the study group, there were 122 soft-tissue sarcomas of various types. The authors used the Kruskal-Wallis non-parametric test and found that there was a statistically significant relationship ($p < 0.0001$) between histologic grade (of all 136 tumors) and median SUVmax:

Tumor Grade	Median SUVmax	Frequency
1	3.0	16
2	5.2	20
3	10.0	100

The authors also found a significant correlation between SUVmax and mitotic count, and between SUVmax and the presence of tumor necrosis. The authors suggested that biopsies should be guided to areas of highest SUVmax to sample the most aggressive areas within a tumor.

Razfar A, Branstetter IV BF, Christopoulos A, et al. Clinical usefulness of PET/CT in recurrent thyroid carcinoma. Arch Otolaryngol Head Neck Surg. 2010 Feb; 136(2): 120-5.

Based on a retrospective case series of patients with histologic evidence of differentiated thyroid carcinoma (DTC, limited to the histologic subtypes of papillary, follicular, or Hürthle cell) who had subsequently been treated with surgical resection and ^{131}I radioiodine ablation, the authors studied the performance characteristics of FDG PET-CT in identifying recurrent thyroid cancer and in contributing to the clinical management of this disease. FDG PET/CT studies were performed using a study-specific patient preparation and scanning protocol. In addition to FDG PET/CT, other imaging modalities included ultrasound (S), whole-body ^{131}I imaging (WBI), CT, or MRI. A positive finding was determined by FDG PET/CT evidence of malignant neoplasm, confirmed either by surgical pathology or by clinical progression. Clinical progression was defined as persistently elevated thyroglobulin (Tg) levels, a rise in Tg level, or progression of disease on serial imaging. Negative findings were clinically benign FDG PET/CT images in combination with negative surgical pathology findings, undetectable Tg levels, or absence of positive findings in serial images. Images were interpreted by one of two experienced head and neck radiologists. Visual interpretations, not SUV criteria, were used to define malignancy. The authors found that patients with treated DTC included 46 men and 76 women, and that their average age was 45 years, ranging from 5 to 85 years. Mean time to follow-up from initial FDG PET/CT was 37 months (range: 1-88 months). The authors calculated the performance characteristics of PET/CT for recurrent (residual) DTC on 124 follow-up FDG PET/CT scans as:

Performance Index	Percent (%)
Sensitivity	80.7
Specificity	88.9
Positive predictive value	94.7
Negative predictive value	65.3

The authors also found that FDG PET/CT results affected clinical management, being decisive in 35/124 patients. Twenty-three of these 35 patients had negative WBI results, and an additional five had negative WBI and US results. Among eight patients with positive WBI results, FDG PET/CT identified distant metastases in five patients that had not been detected on WBI. Negative FDG PET/CT findings prevented unnecessary surgery in three patients with indeterminate or suspicious nodules on US. The authors concluded that FDG PET/CT for detection of recurrent DTC could provide clinical benefit with high diagnostic accuracy in detecting local, regional and distant metastases. However, they recommended that given the well-documented used of Tg levels to monitor for recurrence in treated DTC, FDG PET/CT be reserved for patients whose Tg levels are 10.0 ng/mL or higher, or for those whose Tg levels are rising. The authors acknowledged that a lack of prospective data collection was a limitation of the evidentiary value of their study, and suggested that additional prospective studies would be valuable.

Sharma P, Kumar R, Singh H, et al. Role of FDG PET-CT in detecting recurrence in patients with uterine sarcomas: comparison with conventional imaging. Nucl Med Comm. 2012; 33: 185-90.

In this retrospective study of twelve patients with histologically confirmed uterine sarcomas treated surgically with or without adjuvant therapy (chemotherapy, radiotherapy, or both), the authors' goal was to evaluate the role of FDG PET/CT either for recurrence or for post-therapy surveillance. Patients underwent a study-specific imaging protocol. The reference comparison standards for comparison were clinical or imaging follow-up with and histopathology (when available). Scans were examined by two experienced nuclear medicine physicians, who were unaware of any other imaging or clinical information. The performance characteristics of a diagnostic test were calculated with the 95% confidence interval. The authors found that the twelve patients' median age was 51.5 years, with an interquartile range of 47.5 – 57.3 years. Fifteen FDG PET/CT studies for suspected recurrence or routine surveillance were available on these twelve patients. The performance indices of FDG PET/CT for detecting recurrent disease (on a per-scan basis) were calculated and presented as a table:

Performance Index	PET-CT (95% CI)	Conventional Imaging
Sensitivity	86% (42-98%)	57% (19-89%)
Specificity	100% (69-100%)	88% (44-98%)
Accuracy	93%	73%
Positive predictive value	100% (54-100%)	80% (29-97%)
Negative predictive value	89% (52-98%)	70% (35-93%)

In one patient, PET-CT was falsely negative for a lung metastasis, and in one study PET-CT was falsely negative for local recurrence. However, the authors concluded that there was no statistically significant advantage to PET-CT studies over conventional imaging for detecting recurrence or for routine surveillance. The authors also acknowledge that the sample size was small, perhaps a reflection of recruitment of a relatively uncommon type of tumor from a single medical center. They suggested that further research might be of value.

Skoura E, Rondogianni P, Alevizaki M, et al. Role of [^{18}F] FDG –PET/CT in the detection of occult recurrent medullary thyroid cancer. Nucl Med Commun. 2010; 31: 567-575.

In this retrospective case series of patients with histologically proven medullary thyroid carcinoma (MTC) and elevated calcitonin levels, the authors assessed the diagnostic accuracy of FDG PET/CT for detection of recurrent or persistent disease after thyroidectomy. All patients underwent a study-specific preparation protocol and PET-CT scan. PET-CT images were interpreted by a nuclear medicine physician and a radiologist. True positive findings on images were confirmed by either a) positive histopathology of biopsy; presence at the corresponding site of a detectable lesion by conventional imaging follow-up; or c) increase in lesion size or FDG uptake. False negative images were considered, in view of an elevated calcitonin, any study not showing a clear abnormality. The authors found that for the 32 patients, ten were men and 22 were women. Ages ranged from 21-73 years, with mean age of 52 years. Both hereditary and sporadic types of MTC were present in the study group. Conventional imaging procedures performed on patients in the study group included CT, MRI, ultrasound of the neck, and several types of nuclear medicine scans. True-positive recurrent lesions were mostly in the cervical lymph nodes. The authors calculated that the sensitivity of FDG PET/CT in detecting MTC lesions with either negative or equivocal conventional imaging was 47.4%, with higher sensitivity (about 80%) among patients with calcitonin elevated above 1000 pg/mL. The authors commented that FDG PET/CT was most sensitive in certain circumstances to detect recurrent or metastatic MTC. They suggested that additional research would be of value.

Treglia G, Castaldi P, Villani MF, et al. Comparison of ^{18}F-DOPA, FDG, and ^{68}Ga-somatostatin analogue PET/CT in patients with recurrent medullary thyroid carcinoma. Eur J Nucl Med Mol Imaging. 2012; 39: 569-80.

The authors compared the diagnostic value of FDG PET/CT imaging with various radiotracers for detecting recurrence of medullary thyroid carcinoma (MTC) in patients from three medical centers with prior surgery for MTC and evidence of elevated serum calcitonin levels. Inclusion criteria included: availability of other relevant imaging studies; at least two measurements of carcinoembryonic antigen (CEA) per patient; and availability of either at least twelve months of available clinical follow-up, or of cytohistological diagnosis. The authors found that the study group included 18 patients (six men and twelve women), with a mean age of 53.1 years, ranging from 24 to 86 years. Patients had undergone total thyroidectomy with prophylactic central compartment neck dissection 12 – 192 months (median 90 months) before imaging. All imaging studies were conducted based on institutional protocols. PET/CT images were reviewed independently by two experienced nuclear medicine physicians who were blinded to the original clinical reports. Cytohistological diagnoses were available on eight of 18 study patients. All clinical information was used to determine the presence of recurrent disease; any negative FDG PET/CT results were considered false-negatives. In comparing the three radiotracers' performance, the authors noted that (adapted from Treglia, p. 573) :

Radiotracer	18F-DOPA	68Ga somatostatin analogue	FDG
	Thirteen of 18	Six of 18	Three of 18

Radiotracer	18F-DOPA	68Ga somatostatin analogue	FDG
Study patients with at least one focus of abnormal uptake			
'Sensitivity' (95% CI)	72% (49 – 88%)	33% (16 – 56%)	17% (5 – 40%)

The authors also noted that in eight of 18 patients, results of PET/CT scans led to a change in management. The authors acknowledged the small size of their study as a key limitation. The authors suggested that larger, prospective studies would be valuable to confirm their conclusion that FDG PET/CT was significantly less sensitive for recurrent MTC in patients with elevated calcitonin levels than were other imaging methods, especially ^{18}F-DOPA PET/CT.

Tripathi M, Sharma R, Varshney R, et al. Comparison of FDG and 11C methionine PET/CT for the evaluation of recurrent primary brain tumors. Clin Nucl Med. 2012; 37: 158-63.

Based on a series of patients with a history of treated primary brain tumors referred for evaluation of recurrence, these authors directly compared FDG and ^{11}C methionine PET/CT. Images were collected following a study-specific patient preparation protocol, and images were interpreted independently by two PET physicians. Image results were compared with either histopathology or with clinical follow-up and MRI, which served as reference standards as available. The authors found that the patients included 23 males and twelve females, ranging in age from 5 – 65 years with a mean of 34 years. The timing of PET images after primary tumor diagnosis was 20 months on average, ranging from six to 84 months. Interobserver agreement among interpreters was rated as good for MET (kappa 0.93); whereas for FDG, the authors considered it only fair (kappa 0.23). Findings on MET PET/CT were not significantly different from the reference standard, whereas FDG PET/CT results were significantly different from MET PET/CT results. The authors found that MET PET/CT was more reliable than FDG PET/CT in detecting tumor recurrence, irrespective of tumor grade. The authors concluded that MET PET/CT is more useful in primary brain tumors when MRI is inconclusive. The authors noted that follow-up in this study was relatively short, i.e., for a period of about 18 months.

Yao M, Smith RB, Graham MM, et al. The role of RDG PET in management of neck metastasis from head-and-neck cancer after definitive radiation treatment. Int J Radiat Oncol Biol Phys. 2005; 63(4): 991-9.

In this retrospective single-center study, the authors measured the long-term outcomes of patients managed with post-treatment CT and FDG PET imaging results determining the need for neck dissection. The authors found that, of the 53 assessable patients (42 men and ten women, with median age of 55.5 years (range, 35-77 years)), mean time to FDG PET after completion of treatment was 15 weeks (range, 5-29 weeks). Based on an ROC curve analysis, the cutoff for post-treatment SUV was chosen as 2.9. A summary table below shows the relation of post-treatment FDG PET results (positive or negative, using 2.9 as the cutoff value for SUV, in 70 FDG PET scans following radiation treatment) and persistent/recurrent disease:

Table adapted from Table 2, Yao 2005:

	Persistent/Recurrent Disease:	
Post-RT FDG PET Results:	**Negative FDG PET Scans**	**Positive FDG PET Scans**
Negative	63	0
Positive	4	3

At a median followup of 26 months, no regional failure was identified. The authors concluded that for patients with no evidence of residual lymphadenopathy and a negative FDG PET results twelve weeks after definitive radiation, neck dissection can be safely withheld. If small residual lymphadenopathy is present but the FDG PET result is negative, withholding neck dissection was not associated with local failure. The authors suggested the need for larger prospective studies to determine if, in patients with large residual lymphadenopathy (greater than 2-3 cm in size) but a negative FDG PET result post-treatment, neck dissection can appropriately be withheld.

Case series or case reports:

Choi H, Charnsangavej C, Faria SC, et al. Correlation of CT and PET in patients with metastatic GIST treated at a single institution with imatinib mesylate: proposal of new CT response criteria. J Clin Oncol. 2007 May 1; 25(13): 1753-9.

The purpose of this study was both to determine whether CT changes in advanced gastrointestinal stromal tumors (GIST) from before to after imatinib treatment could be correlated with changes on FDG PET, and to find out if CT criteria (based on tumor size)could be used to evaluate tumor response. 44 patients had both CT and FDG PET within one week of each other before treatment and two months after treatment. Of these 44, four were excluded due to lack of measurable lesions. Among the remaining patients, there were 19 males and 21 females, ranging in age from 28 to 86 years. Lesions less than 1.5 cm in size at baseline were not included for analysis. The authors found that from before treatment to two months after treatment, 33/40 patients with good responses on FDG PET studies (that is, a decrease in SUVmax to below 2.5) showed an average decrease in tumor size of 26%, while those 7/40 with poor responses showed a size increase of 10%. In those with good responses by FDG PET, tumor density decreased by 15% or more in 27/33 (82%) of patients. In those with poor responses by FDG PET, 7/40 patients showed no tumor size or density decrease. The authors commented that with these criteria for 'good' and 'poor' response to treatment for GIST, FDG PET was useful to demonstrate treatment response to imatinib even in cases in which CT measurements did not show changes in tumor volume or density.

4. MEDCAC

A Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting was not convened on this issue.

5. Evidence-based guidelines

The American College of Radiology provides guidelines for imaging for specific clinical situations, (for example, Lee 2010 regarding imaging for patients with uterine (endometrial) cancer with suspected recurrence after therapy). This guideline rates FDG PET/CT 'highly appropriate' in this situation but notes the relatively high radiation level involved.

However, a note in the Lee 2010 guideline explains that the guideline was developed by consensus (modified Delphi method). The guideline also notes that, for FDG PET/CT, "The role of positron emission tomography (PET) in endometrial cancer imaging is still under investigation."

number of evidence based recommendations for use of FDG PET in therapeutic clinical trials have been proposed (for example, Scher 2004) but were not further reviewed for this coverage determination about FDG PET use in subsequent treatment strategy planning (following completion of initial therapy) in non-research settings.

6. Professional Society Position Statements

Several professional societies commented on the proposed decision determination and can be read in their entirety under the Public Comments section below.

7. Expert Opinion

CMS did not solicit any expert opinions on ending the prospective data collection requirements under CED for specific oncologic indications. Several public comments expressed the views of experienced oncologists, radiologists and nuclear medicine physicians on the use of FDG PET for subsequent treatment strategy planning.

8. Public Comments

Initial Comment Period: September 12, 2012 through October 12, 2012

CMS received 82 public comments during the first public comment period. Of those, 77 supported the request to end CED for all oncologic indications for FDG. Comments were received from medical and surgical oncologists, nuclear medicine physicians, general radiologists, other physicians, FDG PET facilities, industry associations and other sources. Any articles submitted with these public comments were not unique to those submitted by the requestor or identified by CMS during its literature review.

Second Comment Period: March 13, 2013 through April 14, 2013

CMS received 201 timely public comments during this period. Comments were received from beneficiaries, university and private cancer centers, nuclear medicine physicians, medical and surgical oncologists, professional ·ocieties, PET facilities, industry associations and others. CMS thanks those commenters that submitted eferences relevant to this review to assist in our decision making process. Twelve comments were not relevant to this topic.

Comment:

None of the commenters expressed opposition to ending the data collection requirements under CED for all oncologic indications for FDG PET.

Response:

CMS appreciates the support expressed in these comments.

Comment: CMS received 175 comments opposing the proposed one scan limitation of covered FDG PET scans used to guide subsequent physician management of anti-tumor treatment strategy after completion of initial anti-tumor treatment strategy. Some commenters recognized that we had also proposed that coverage of additional scans beyond one would be determined by the local Medicare Administrative Contractors (MACs.) Various commenters including the requestor noted that 3 scans was a typical number for patients undergoing second or third line anticancer treatment.

Response:

CMS appreciates these comments and will nationally cover at least three additional scans. Coverage of additional scans (that is, more than three) shall be determined by the local MACs.

Comment:

CMS received 23 comments in favor of covering FDG PET scans for the subsequent anti-tumor treatment strategy of prostate cancer. Commenters cited evidence that advanced hormone refractory prostate cancer demonstrates avidity for FDG, in contrast to the lack of FDG avidity in earlier prostate cancer. CMS also received seven comments from those requesting that CMS non-cover FDG PET for subsequent anti-tumor treatment strategy for prostate cancer.

Response:

CMS reviewed additional evidence and will nationally cover FDG PET for subsequent anti-tumor treatment strategy of prostate cancer. This is further discussed in the Analysis section below.

Comment:

Several commenters believed that certain language in the proposed decision memorandum was unclear with respect to the scope of the analysis and the proposed manualization of PET coverage.

Response:

CMS has revised this language such that the scope of this analysis includes all oncologic uses of FDG PET, not just those that are currently covered under CED.

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1869(f)(1)(B) of the Act). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See §1862(a)(1)(A) of the Act. This section presents the agency's evaluation of the evidence considered and conclusions reached for the assessment.

We are mindful of our past considerations of this topic, and in particular our April 2009 reconsideration, which included a review of CED derived evidence. In that decision we wrote in part "... the publication of results derived from NOPR and the advances in the current evidence base, which consistently note the physicians' use of FDG PET imaging results to guide management for several cancer indications, we believe that we have sufficient evidence to support broader FDG PET coverage for use in solid tumors in the context of initial treatment strategy..."

CMS' approach to this analysis is consistent with that expressed in 2009 (emphasis in bold by CMS):

"Ideally (from the standpoint of coverage decision-making), evidence about the clinical effect of any additional FDG PET scan for initial treatment planning would show benefits in healthcare outcomes compared to similar patients in whom any additional FDG PET scan for initial treatment planning was not performed. However, as noted in the Facey et al., 2007 evidence review (CMS note (2013): cited in bibliography as Facey 2007), such findings about improved healthcare outcomes are limited. ... (P)ublished evidence from clinical studies about the benefit of any additional FDG PET scan ... demonstrating changes in RT management or, less often, on studies demonstrating changes in treatment strategy (from intended cure to palliation) due to detection of distant metastases, undetected at the time of initial staging studies. In the future, we hope that additional clinical studies would focus on indicators of outcomes such as better local tumor control and longer patient survival. (Source: Section VIII, CMS reconsideration of FDG PET in initial ATS planning, Medicare National Coverage Database document CAG-00181R3 (2009). Emphasis in bold font added by CMS, 2013.)"

The Medicare regulations at 42 CFR § 410.32(a) state in part, that "...diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Thus, we looked for evidence demonstrating how the treating physician uses the result of any additional FDG PET scan for treatment planning after completion of initial therapy, i.e. for the guidance of subsequent anti-tumor treatment strategy.

We considered the evidence in the efficacy framework of Fryback and Thornbury (1991) ('FT') where FT Level 2 addresses diagnostic accuracy, sensitivity, and specificity of the test; FT Level 3 focuses on whether the information produces change in the physician's diagnostic thinking; FT Level 4 concerns the effect on the patient management plan and FT Level 5 measures the effect of the diagnostic information on patient outcomes. We believe that evidence of improved health outcomes, such as treatment options offering prolonged survival, and diagnostic evidence supporting changes in therapeutic management, is more persuasive than evidence of test characteristics.

In evaluating diagnostic tests, Mol and colleagues (2003) reported: "Whether or not patients are better off from undergoing a diagnostic test will depend on how test information is used to guide subsequent decisions on starting, stopping, or modifying treatment. Consequently, the practical value of a diagnostic test can only be assessed by taking into account subsequent health outcomes." When a proven, well established association or pathway is available, intermediate health outcomes may also be considered. For example, if a particular diagnostic test result can be shown to change patient management and other evidence has demonstrated that those patient management changes improve health outcomes, then those separate sources of evidence may be sufficient to demonstrate positive health outcomes from the diagnostic test.

While survival may be the most obvious outcome in cancer, we recognize that individual patients may follow better or worse paths even if both paths ultimately end in death. Cancer and its treatments may lead to significantly disabling symptoms such as pain, weakness, neuropathy, vomiting and infection to name only a few.

We also note that patients may not respond successfully to initial antitumor strategy for a number of reasons, e.g. ineffectiveness of the treatment, intolerability of the treatment, and that specific reasons may vary among patients. Thus, patients who are considered for subsequent anti-tumor treatment have already been unsuccessfully treated. This history may weigh heavily on the choices among available treatments.

As illustrated in the evidence section of this DM, many studies were considered during our review of this topic area. These studies included not only those of cancer types covered as CED under previous NCDs, but also other types of solid tumors. We used not only the studies of Hillner and colleagues in the National Oncologic Pet Registry (NOPR), but also evidentiary findings of published articles about clinical studies of FDG PET/CT as a diagnostic method, a number of which have been contributed by public commenters. Although we particularly looked for evidence at FT level 5 to more directly tie FDG PET to improvements in patient health outcomes, we also looked for evidence on the impact of FDG PET on the treating physician's management of patients.

NOPR Findings

In general, evidence derived from NOPR data indicate that FDG PET result changes physician's self-reported management, with reported means of approximately 35-40 percent. As discussed elsewhere, the NOPR methodology has a number of strengths: for example, the numbers of patients included in the NOPR-derived studies are larger by orders of magnitude than the numbers in other clinical studies, and reflect a large variety of healthcare settings in many areas of the U.S. However, methodological limitations include: the sources of NOPR's findings are self-reported, uncontrolled physician assessments of intended management; NOPR findings were generally based on pre- and post-imaging interpretation at the same imaging facility; there were admitted definitional problems for certain key outcomes (re-staging), and inconsistency with other studies (as recognized in NOPR publications, e.g., Hillner 2011).

Perhaps the primary shortcoming that has been recognized by NOPR's authors is that their findings are limited to FT Level 3: evidence that FDG PET/CT imaging results change the physician's intended patient management (not actual changes in management or outcomes). An early article about NOPR's design and its analysis plan concluded "(t)he NOPR will allow an accurate assessment of the impact of PET on intended patient management across a wide spectrum of cancer indications" (Lindsay 2007). CMS agrees with the comment (Hillner 2011) indicating that "(a) major limitation of the NOPR is the inability to determine whether the intended changes in management confer a benefit in long-term outcomes."

Nevertheless, NOPR-derived results have informed our consideration of the evidence base for covering FDG PET imaging for this oncologic indication. We are also mindful that anticancer treatment largely depends on advanced diagnostic imaging results that influence physician decision making. The practical decisions include for example, whether to pursue primarily curative or palliative strategies, or whether to administer treatments with risk of lethality. In the setting of anticancer treatment we believe that the choices made by treating physicians in many instances change the patient's experience of illness. Therefore we have largely accepted the persuasiveness of the NOPR report, except where we believe there is other evidence available to better support an alternative conclusion. This relationship of reported change in management to patient outcomes may not be apparent in other clinical contexts where the impact or the rationality of physician choice is more ambiguous.

Additional analyses are described below for specific tumor types that had been covered in prior NCDs under CED, with particular attention to evidence derived from non-NOPR data.

Primary brain malignancies

Clinical studies of FDG PET's role in detecting recurrence of primary brain tumors following initial treatment has been described in several articles, including: Enslow 2012; Santra 2012; Tan 2011; Tripathi 2012. However, these studies reflect at best FT Level 2 (as previously discussed).

The Enslow 2012 article compared FDG PET with gadolinium-MRI for differentiating radiation necrosis from recurrent glioma. However, the authors' description of the demographic characteristics of their small (n = 15) case series did not provide sufficient detail to know whether this study is characteristic of the senior Medicare patient population. We also note that a potential interference with FDG PET readings may arise from the high glucose metabolism in cerebral cortex (for example, Enslow 2012). However, a technique to minimize this effect has been suggested: confirmation of a suspected recurrent tumor in one cerebral hemisphere can best be identified by a ratio to contralateral FDG activity in unaffected white matter (Enslow 2012).

CMS did find evidence of FDG PET's contribution to changing patient management. The Enslow 2012 study found that FDG SUVmax could differentiate between recurrent disease and radiation fibrosis. Also, in the Hillner 2011 study, 274 FDG PET scans were performed in participants with primary brain tumors, both for restaging, and for detection / confirmation of suspected recurrences. A larger effect on intended treatment was found in those with primary brain tumors than those in the overall NOPR cohort.

For the above reasons, CMS concludes that the evidence supports the use of FDG PET as reasonable and necessary in the management of recurrent primary brain tumors, and thus is appropriate for Medicare coverage under § 1862(a)(1)(A).

Pancreatic cancers

Clinical studies of FDG PET's role in detecting recurrence of primary pancreatic tumors following initial treatment has been described in several articles, including: Hillner 2012; Kitajima 2010; Sperti 2010; Topkan 2011. Topkan 2011 also studied FDG PET's role in evaluating treatment response. Except for the Hillner 2012 article, these reflect studies of FDG PET/CT diagnostic performance (FT Level 2) in patients with pancreatic cancers.

The Kitajima 2010 article compared performance characteristics of FDG PET with contrast-enhanced CT to FDG PET with unenhanced CT for diagnosing recurrence pancreatic cancer. They found that, using a combination of histopathology findings and radiologic imaging follow-up as the combined gold standard, the sensitivity of FDG PET with contrast-enhanced CT was 83% for recurrence.

The authors of the Hillner 2012 article looked at the impact of FDG PET on intended management in more than 7,000 scans undergone by Medicare beneficiaries of pancreatic cancer, and found that in about 40% of cases physicians reported a likely change in post-PET intended management.

Sperti 2010 found that in 72 treated pancreatic cancer patients with 63 recurrences, FDG PET was positive in 61 patients when CT was non-diagnostic. These authors also found that treatment was changed by FDG PET results in 32 of 72 patients (44%).

For the above reasons, CMS concludes that the evidence supports the use of FDG PET as reasonable and necessary in the management of recurrent pancreatic tumors, and thus is appropriate for Medicare coverage under § 1862(a)(1)(A).

Prostate cancers

As reflected in the proposed decision memorandum (PDM), CMS found little evidence about effects of FDG PET on outcomes for patients whose initial therapy for prostate cancer had been completed. Current literature on PET tracers for recurrence or tumor response seemed to focus mainly on a different radiopharmaceutical, ^{11}C choline.

However, public comments about the PDM indicated that evidence of the value of FDG PET scans was in some cases provided in therapeutic studies and was also available in more recent articles. After review of these important components of the evidence base, CMS agrees that a significant benefit of FDG PET scans is their use to determine effect of treatment, especially at certain types of progressive prostate disease.

As examples of the importance of this, NOPR findings (e.g., Hillner 2012) indicate that in about 40% of instances, physicians would change their intended therapy for patients with prostate cancer. Despite the known concerns about lack of glucose avidity of prostate cancer cells, as mentioned in Hillner 2009other studies indicated that FDG PET CT could be valuable even for assessing activity of bone metastases of prostate cancers in a large majority of patients (Meirelles 2010).

Nevertheless, we are convinced that FDG PET/CT imaging's selective use in assessing progression of prostate cancer does provide valuable additional information for managing treatment decisions, and therefore we consider its use for subsequent treatment strategy planning to be reasonable and necessary. We note that in many of these studies, a rising PSA level was key to the clinical suspicion of progressive or recurrent prostate cancer.

We also agree with the NOPR public comments emphasizing that physicians were found to selectively employ FDG PET for subsequent anticancer treatment planning in appropriate patients. We expect that post-coverage analysis ('PCA) review by CMS will confirm this NOPR observation.

Consequently, CMS proposes that use of FDG PET/CT when used to guide subsequent anti-tumor treatment strategy for patients with cancer of the prostate is reasonable and necessary under § 1862(a)(1)(A).

Soft tissue sarcomas

Studies of use of FDG PET/CT for treatment response (to imatinib chemotherapy) in GIST are available (e.g., Choi 2007). Other authors suggest that post-treatment PET imaging provides benefit by identifying distant metastases, in neither circumstance is evidence provided about improvement in beneficiaries' outcomes. Other studies show changes in intended treatment management for more than 28% of participants with soft tissue sarcomas in a NOPR-based study (Hillner 2008B).

Therefore, CMS finds that there is evidence that FDG PET/CT influences physician decision-making in beneficiaries with soft tissue sarcomas after completion of initial anticancer therapy. Under § 1862(a)(1)(A), CMS proposes that use of FDG PET in this context is reasonable and necessary and that its use be covered by the Medicare program.

Testicular cancers

Clinical studies (e.g., Huddart 2007) suggest that in patient with potential for recurrence after orchiectomy, FDG PET/CT imaging was associated with an unacceptably high rate of relapse (33 relapses (38%)) among (87) FDG PET negative nonseminomatous germ cell tumor patients). (Hillner 2012 does not include de-aggregated data about the effect of FDG PET/CT imaging on restaging or suspected recurrence.)

CMS found no evidence regarding the effect of FDG PET on patient outcomes. We note that testicular cancers are lumped with other solid tumors in NOPR-based studies. Nevertheless, we conclude that although additional studies might be valuable, the existing evidence base provides support for the use of FDG PET to guide therapy in beneficiaries with testicular cancer after completion of primary anticancer therapy. Therefore, CMS finds that Medicare coverage is appropriate for this indication under § 1862 (a)(1)(A).

Thyroid cancers

A number of clinical studies have examined the use of FDG PET/CT for detecting recurrence of various types of thyroid cancer, including: Bannas 2012, Choi 2010, Conry 2010, Dahele 208, Giovanella 2012, Na 2012, Ozkan 2011, Ozkan 2012, Razfar 2010, Rubello 2009, Seo 2010, Skoura 2010, and Treglia 2012. (Note: Hillner 2012 presents aggregated counts of all types of thyroid cancer in assessing the possible effects of FDG PET/CT findings on physicians' post-treatment management strategy.) The following table prepared by CMS briefly summarizes the key findings of these studies, and the FT Levels of evidence supported:

Study	Indication	FT Level
Bannas 2012	In a consecutive case series (n = 30), FDG PET showed89% positive predictive value in detecting recurrent DTC.	2
Choi 2010	In 76 patients with papillary thyroid cancer after treatment, FDG PET was less sensitive and specific for detecting recurrence than neck ultrasound; but differences were not statistically significant. Either method of detecting recurrence led to treatment changes in 30 - 40% of patients.	3
Conry 2010	In a series (n = 18) the diagnostic performances of FDG PET/CT and ^{68}Ga-DOTATATE in detecting recurrences of medullary thyroid cancer were compared. Sensitivities of the two methods were not statistically significant.	2
Dahele 2008	In 15 patients with treated papillary thyroid cancer, FDG PET was able to detect regional or distant recurrence in patients with low Tg levels	2

Study	Indication	FT Level
Giovanella 2012	FDG PET/Ct detected recurrent DTC after therapy with a sensitivity of 93% and a specificity of 84%	2
Na 2012	In this retrospective study of differentiated thyroid cancers, the authors found that sensitivity of FDG PET/CT increased with higher Tg levels, going from 29% at Tg levels of 2-5 ng/mL, to 86% at Tg levels of 20 ng/mL or more.	2
Ozkan 2011	In patients with medullary thyroid cancer after treatment, who had elevated calcitonin levels, FDG PET showed sensitivity of 93% and specificity of 68%.	2
Ozkan 2012	FDG PET/CT detected recurrent DTC in patients with anti-Tg levels, with a sensitivity of 74% and a specificity of 75%	2
Razfar 2010	FDG PET/CT was useful for detecting local, regional and distant recurrence of differentiated thyroid cancers, with sensitivity and specificity of 81% and 89%, respectively.	2
Rubello 2009	In 19 patients with recurrent MTC, FDG PET/CT was the most sensitive imaging modality (compared to results of ^{111}In pentetreotide, CT, and US), using cyto- or histopathology findings as the gold standard.	2
Seo 2010	Among patients with anti-Tg, FDG PET showed sensitivity of 76% and specificity of 87% in detecting recurrent differentiated thyroid cancer.	2

Study	Indication	FT Level
Skoura 2010	In patients with treated medullary thyroid cancer and elevated calcitonin levels (10 or more pg/mL), sensitivity of FDG PET/CT was nearly 100% in detecting recurrence if calcitonin was elevated above 1000 pg/mL.	2
Treglia 2012	FDG PET/CT was less sensitive (17%) than other methods, especially F-18 DOPA PET/CT (72%) in detecting recurrence of treated medullary thyroid cancer.	2

Several of the studies above used thyroglobulin (Tg) levels to detect recurrence of thyroid cancer, and noted that either radioactive iodine or FDG PET/CT are available to locate any recurrence(s). However, no studies directly examined the effect of FDG PET/CT imaging on improving outcomes for patients treated for any types of thyroid cancer.

Based on the above findings of diagnostic utility and changes in patient management, CMS finds that the evidence is sufficient to conclude that use of FDG PET imaging to guide subsequent anti-tumor strategy in beneficiaries who have completed initial anticancer therapy for thyroid cancer is reasonable and necessary in the context of § 1862(a)(1)(A).

All other solid malignant tumors

CMS recognizes the futility of attempting to conduct clinical trials covering all types and subtypes of solid malignant tumors. Therefore, we reviewed the findings about 'all other cancers' as tabulated above (Hillner 2012). We conclude that in the many beneficiaries with such tumors, FDG PET was associated with a 33-34% change in intended subsequent patient management.

Accordingly, CMS finds that available evidence supports use of FDG PET to influence physician management of beneficiaries with solid tumors other that those discussed above, and consequently proposes national Medicare coverage as reasonable and necessary in the context of § 1862(a)(1)(A).

In summary, based on evidence from NOPR and other sources that FDG PET imaging changes physician management, CMS concludes that physicians are able to use the results of this diagnostic test in the treatment of patients with brain, pancreas, prostate, soft tissue sarcoma, small cell (of lung), thyroid, testis, and any other solid cancer. We further conclude that FDG PET is reasonable and necessary to guide anti-tumor strategy in beneficiaries with these various types of cancer after completion of initial anti-tumor therapy, and therefore is appropriate for coverage under § 1862(a)(1)(A). CMS therefore removes the requirement for CED for these tumor types, in response to the current request for reconsideration.

Concerns about FDG PET utilization

In our proposed decision, we discussed a concern that Medicare might inadvertently make payment for 'routine surveillance' with FDG PET (that is, FDG PET imaging of asymptomatic patients without clinical evidence of recurrence after completion of initial anticancer therapy, in whom no active anticancer decision making is occurring). Many public commenters agreed with us on this underlying principle, but questioned when unnecessary 'surveillance' began in the context of actual medical practice and patient care. Thus, in the preliminary decision memo we proposed permitting local Medicare Administrative Contractors to make the determination of medical necessity for additional scans beyond one used in subsequent anti-tumor treatment strategy.

However, based on public comments and additional NOPR data analysis (communicated to CMS by Dr. Hillner) we are now aware that many patients may expect to undergo more than one FDG PET scan during later phases of their medical treatment. CMS recognizes that a patient who has not been successfully treated with initial anti-tumor therapy might be a candidate for 'second line' or even further treatment, and there might be instances where additional FDG PET scans can be appropriately informative, depending on pertinent facts that can be found in the patient's medical documentation. Therefore, in this final decision memo we permit local Medicare Administrative Contractors to determine coverage for additional FDG PET scans beyond three used in subsequent anti-tumor treatment strategy.

This determination will both provide administrative flexibility to enhance patient access to needed medical care, and reduce potential overutilization of FDG PET scans that would not be found to be reasonable and necessary. Published data (Dinan 2010) examined the annual increase in FDG PET scans among Medicare beneficiaries with cancer of all types, and found utilization of FDG PET diagnostic imaging in patients with cancer rose each year from 35.9%-53.6% from 1999 through 2006. We realize that establishing a numerical criterion for nationally covered FDG PET scans subsequent to completion of initial therapy CMS has the potential to inform medical review activity by local Medicare administrative contractors.

Health disparities

A review of articles discussed above in this decision memorandum reveals no analysis of outcome by racial or ethnic categories. Any inference about relative benefits positron emission tomography in specific racial or ethnic groups would be speculative. CMS also notes the absence of evidence about benefits or harms related to other population classifiers that have been associated historically with healthcare access or outcome disparities, such as gender, sexual orientation, religion, and age, and encourages additional studies in which such associations might be studied.

Results of cancer therapy continue to demonstrate racial/ethnic as well as socio-economic disparities. The authors of ACS 2012 stated that lack of health insurance and other barriers prevents many Americans from receiving optimal health care. This included, according to a US Census Bureau study in 2009, no health insurance coverage for one-third of Hispanics and one in ten children. Uninsured patients and those from ethnic minorities are more likely to be diagnosed with cancer at a later stage. At this point in the disease, treatment must be more extensive to be effective (ACS 2012).

African Americans are more likely to develop and die from cancer than any other racial or ethnic group. African American men have higher incidence and mortality rates than whites for each of the eight most frequent cancer sites (breast, colorectal, kidney, liver and intrahepatic bile duct, lung and bronchus, prostate, stomach, and uterine cervix), except for kidney cancer, for which the rates are the same (ACS 2012).

Persons with lower socioeconomic status (SES) have disproportionately higher death rates that those with higher SES. Lower SES is also associated with lower access to preventive services and to lower literacy rates. Behaviors that increase cancer risk, including tobacco use, lack of physical activity, and poor diet are more likely among those with lower SES. Progress in reducing cancer death rates has been slower in persons with lower SES (ACS 2012).

Genetic and cultural/familial behavioral factors may also drive cancer risk in selected minority groups. As examples: higher risk of breast and ovarian cancer among Ashkenazi Jews is believed to be due to increased frequency of mutations in *BRCA1* and *BRCA2*;and earlier childbearing among Hispanic women is thought to lower breast cancer risk (ACS 2012).

CMS recognizes that recent publications may reflect additional interest in examining disparities in PET use among geographic or sociodemographic population subgroups. A recent retrospective article examined disparities in FDG PET use by Medicare beneficiaries with cancer (Onega 2012). Using CMS files, Medicare claims for beneficiaries with any of five selected cancers (head and neck; lung; esophageal; colorectal; and lymphoma, based on icd-9-cm coding of the claim) were tabulated and examined in relation to a number of economic and demographic factors. Beneficiaries in Medicare advantage plans were excluded, as were beneficiaries less than 65 years old or more than 100 years old. The authors found that in the study population of cancer patients, the median age was 75 years, and 48% of study subjects were female. They found that PET use among beneficiaries with cancer increased from 2004 to 2008. In each of those years, PET use was higher among whites than among blacks. The authors concluded that the growth from 2004 to 2008 was not uniform across health care markets or patient populations.

CMS concludes that there is a need for additional evidence about racial and ethnic factors. In our view this evidence gap should be considered by trial designers when proposing future clinical trial designs. All other factors being equal, CMS will prefer clinical study proposals in which data on racial and ethnic factors are specifically collected and analyzed.

Summary:

a. *Is the evidence adequate to conclude that the results of an FDG PET scan will meaningfully improve health outcomes in beneficiaries who have completed an initial treatment regimen for any of the following types of solid tumors: brain, pancreas, prostate, soft tissue sarcoma, small cell (of lung), thyroid, testis, or for any other solid malignant tumor?*

b. Is the evidence adequate to conclude that the results of an FDG PET scan will guide physician management of subsequent anti-tumor treatment strategy in beneficiaries who have completed an initial treatment regimen for any of the following types of solid tumors: brain, pancreas, prostate, soft tissue sarcoma, small cell (of lung), thyroid, testis, or for any other solid malignant tumor?

We have not found direct evidence that results of FDG PET imaging improve health outcomes, despite references provided by public commenters. Thus we determine that the answer to question a) is "no". However, the answer to question b) is, we believe, "yes".

IX. Conclusion

A. The Centers for Medicare & Medicaid Services (CMS) has determined to end the requirement for coverage with evidence development (CED) under §1862(a)(1)(E) of the Social Security Act (the "Act') for ^{18}F fluorodeoxyglucose positron emission tomography (FDG PET) for oncologic indications which are contained in section 220.6.17 of the Medicare National Coverage Determinations Manual. This removes the requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for those cancers or cancer types that had been covered under CED (as listed in Appendix A).

B. CMS has determined that three FDG PET scans are covered under § 1862(a)(1)(A) when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anticancer therapy. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy will be determined by local Medicare Administrative Contractors.

See Appendix C for NCD manual language.

Appendix A: Summary of Coverage with Evidence Development (CED) Requirements for Oncologic Indications, as of September 2012
[Reference: CAG-00181R (2009), Appendix A.
Note: 'ATS' denotes anti-tumor treatment strategy]

Solid Tumor Type	Initial ATS	Subsequent ATS
Cervix uteri	1 or CED	Cover
Brain	Cover	CED
Pancreas	Cover	CED
Prostate	Non-cover	CED
Small cell lung	Cover	CED
	Cover	CED

Solid Tumor Type	Initial ATS	Subsequent ATS
Soft Tissue Sarcoma		
Testes	Cover	CED
Thyroid	Cover	2 or CED
All other solid tumors	Cover	CED
All other cancers not listed (see note below) in Appendix A, CAG-00181R (2009)	CED	CED

(1) Cervix: Nationally non-covered for diagnosis of cervical cancer. Covered for detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer if prior conventional imaging is negative for extra-pelvic metastases. All other uses are CED.
(2) Thyroid: Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are CED.

Note: Tumors listed in Appendix A, CAG-00181R (2009) for coverage, non-coverage or CED for either initial or subsequent ATS included the following:

Brain; cervix (uteri); colon and rectum; esophagus; head and neck (except thyroid and CNS); myeloma; pancreas; prostate; lymphoma; melanoma; ovary; pancreas; prostate; small-cell and non-small cell cancers of lung; soft tissue sarcoma; and testes.

APPENDIX B
General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.

Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.

Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.

arger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.

Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).

Co-interventions or provision of care apart from the intervention under evaluation (performance bias).

Differential assessment of outcome (detection bias).

Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed an conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e.g., using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix C

220.6.17 - Positron Emission Tomography (FDG PET) for Oncologic Conditions - (Various Effective Dates) (Rev.)

General

FDG(2-[F18] fluoro-2-deoxy-D-glucose) PET is a minimally-invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. FDG is an injected radionuclide (or radiopharmaceutical that emits sub-atomic particles, known as positrons, as it decays. FDG PET uses a positron camera (tomograph) to measure the decay of FDG. The rate of FDG decay provides biochemical information on glucose metabolism in the tissue being studied. As malignancies can cause abnormalities of metabolism and blood flow, FDG PET evaluation may indicate the probable presence or absence of a malignancy based upon observed differences in biologic activity compared to adjacent tissues.

The Centers for Medicare and Medicaid Services (CMS) was asked by the National Oncologic PET Registry (NOPR) to reconsider section 220.6 of the National Coverage Determinations (NCD) Manual to end the prospective data collection requirements under Coverage with Evidence Development (CED) across all oncologic indications of FDG PET imaging. The CMS received public input indicating that the current coverage framework of prospective data collection under CED be ended for all oncologic uses of FDG PET imaging.

1. Framework

Effective for claims with dates of service on and after June 11, 2013, CMS is adopting a coverage framework that ends the prospective data collection requirements by NOPR under CED for all oncologic uses of FDG PET imaging. CMS is making this change for all NCDs that address coverage of FDG PET for oncologic uses addressed in this decision. This decision does not change coverage for any use of PET imaging using radiopharmaceuticals NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82).

2. Initial Anti-tumor Treatment Strategy

CMS continues to believe that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial anti-tumor treatment strategy for beneficiaries with suspected cancer and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the "Act").

Therefore, CMS continues to nationally cover one FDG PET study for beneficiaries who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

See the table at the end of this section for a synopsis of all nationally covered and non-covered oncologic uses of FDG PE imaging.

Initial Anti-Tumor Treatment Strategy Nationally Covered Indications Effective June 11, 2013

a. CMS continues to nationally cover FDG PET imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.

b. CMS continues to nationally cover FDG PET to determine initial anti-tumor treatment strategy for melanoma other than for the evaluation of regional lymph nodes.

c. CMS continues to nationally cover FDG PET imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers.

Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications Effective June 11, 2013

a. CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate. CMS continues to nationally non-cover FDG PET imaging for diagnosis of breast cancer and initial staging of axillary nodes.

b. CMS continues to nationally non-cover FDG PET imaging for initial anti-tumor treatment strategy for the evaluation of regional lymph nodes in melanoma.

c. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

3. Subsequent Anti-tumor Treatment Strategy

Subsequent Anti-Tumor Treatment Strategy Nationally Covered Indications Effective June 11, 2013

Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy. Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy shall be determined by the local Medicare Administrative Contractors.

4. Synopsis of Coverage of PET FDG for Oncologic Conditions Effective June 11, 2013

Effective for claims with dates of service on and after June 11, 2013, the chart below summarizes national FDG PET coverage for oncologic conditions:

FDG PET for Solid Tumors and Myeloma Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" and "monitoring response to treatment")
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid or CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover

FDG PET for Solid Tumors and Myeloma Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" and "monitoring response to treatment")
Cervix	Cover with exceptions *	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	**Non-cover**	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.

*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.

*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti -tumor treatment strategy for melanoma are nationally covered.

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Variations in Use of PET among Medicare Beneficiaries with Non–Small Cell Lung Cancer, 1998–2007

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Abstract

Purpose: To explore demographic and regional factors associated with the use of positron emission tomography (PET) in patients with non–small cell lung cancer (NSCLC) and to determine whether their associations with PET use has changed over time.

Materials and Methods: The Office of Human Research Ethics at the University of North Carolina and the institutional review board of the Duke University Health System approved (with waiver of informed consent) this retrospective analysis of Surveillance Epidemiology and End Results Medicare data for Medicare beneficiaries given a diagnosis of NSCLC between 1998 and 2007. The primary outcome was change in the number of PET examinations 2 months before to 4 months after diagnosis, examined according to year and sociodemographic subgroup. PET use was compared between demographic and geographic subgroups and between early (1998–2000) and late (2005–2007) cohorts by using χ^2 tests. Factors associated with use of PET during the study period were further examined by using logit and linear probability multivariable regression analyses.

Results: The final cohort included 46 544 patients with 46 935 cases of NSCLC. By 2005, more than half of patients underwent one or more PET examinations, regardless of demographic subgroup. In multivariable logistic regression analysis, patients who underwent PET were more likely to be married, nonblack, and younger than 80 years and to live in census tracts with higher education levels or in the Northeast ($P < .001$ for all). Living within 40 miles of a PET facility was initially associated with undergoing PET ($P < .001$), but this association disappeared by 2007. Imaging rates increased more rapidly in patients who were nonblack ($P \leq .01$), patients who were younger than 81 years ($P < .001$), and patients who lived in the Northeast and South ($P < .001$).

Conclusion: PET imaging among Medicare beneficiaries with NSCLC was initially concentrated among nonblack patients younger than 81 years. Despite widespread adoption among all subgroups, differences within demographic subgroups remained.

Footnotes

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Abbreviations:
NSCLC = non–small cell lung cancer
SEER = Surveillance Epidemiology and End Results