Technology and Equipment Committee Meeting

Linear Accelerator Material

April 29, 2009

~~Radiation Oncology Services~~ – Linear Accelerators

Introduction

The methodology incorporates a geographic accessibility criterion (a population base of 120,000), a criterion aimed at assuring efficient use of megavoltage radiation facilities (when Equivalent Simple Treatment Visit (ESTV) procedures divided by 6,750 minus the number of present linear accelerators equals .25+), and a patient origin criterion that indicates when a service area has 45 percent or more of the patients coming from outside the service area. A need determination is generated when two of the three criteria are met within a service area.

Counties are the basic units for the formation of ~~radiation oncology~~ linear accelerator service areas, based on proximity, utilization patterns, and patient origin data. A small percentage of the population lives some distance from ~~an existing radiation oncology facility~~ a linear accelerator, but the sparsity of population in and around these areas does not provide the population required to support a ~~radiation oncology facility~~ linear accelerator.

The statewide average number of procedures per accelerator as shown in Table 9E is 4,973.

~~Radiation Therapy~~ Assessment -- Linear Accelerators

Radiation therapy (megavoltage radiation) is used in the treatment of about half of all cancers. Its users seek to destroy cancer cells with ionizing radiation while limiting damage to non-cancerous tissue. <u>Linear accelerators</u> are now the instruments of choice because most are capable of producing either electron or photon beams at variable energy levels.

In the 2009 Hospital Licensure Renewal Applications, which reflect 2008 data, there are 14 linear accelerators in nine different locations in North Carolina reported as being operational and providing stereotactic radiosurgery treatment: Carolinas Medical Center (115 procedures); CMC-NorthEast (240 CyberKnife procedures); Duke University Hospital (272 procedures on two linear accelerators); Memorial Mission Hospital (339 CyberKnife procedures); Pitt County Memorial Hospital (__ procedures on two linear accelerators, reported as being owned by Brody School of Medicine); UNC Hospitals (381 procedures on four linear accelerators configured for stereotactic radiosurgery, including one CyberKnife); Wake Forest University Baptist Medical Center (__ procedures on one linear accelerator configured for stereotactic radiosurgery); Forsyth Memorial Hospital (73 procedures on one linear accelerator configured for stereotactic radiosurgery); and North Carolina Radiation Therapy Management Services in Asheville (five procedures on one linear accelerator configured for stereotactic radiosurgery).

In recent years, radiation therapy has been offered increasingly in comprehensive oncology programs where medical oncologists and hematologists also offer chemotherapy. Most such programs are associated with general hospitals, but some are freestanding. Some programs offering <u>only</u> radiation therapy, or <u>only</u> chemotherapy, may refer to themselves as oncology centers. A new radiation oncology facility, with necessary equipment, usually costs about $2,000,000.

~~Assessment - Radiation Oncology Programs~~

In addition to a linear accelerator, every radiation oncology program uses a treatment simulator to aid in treatment planning, a computer for calculating dosages, and devices for cutting blocks to protect non-targeted areas from radiation. One simulator, which is the most expensive of these additional items ($200,000 - $400,000), can serve a facility with three linear accelerators or serve multiple facilities with linear accelerators. The specialized staff who operate and maintain this equipment, including a required radiation physicist, are more efficiently utilized in facilities with more than one linear accelerator.

~~Presently, existing radiation oncology programs are reasonably convenient to the population of the state. The high cost of establishing new programs and the possibilities for achieving further equipment and staff economies of scale are critical considerations in evaluating the need for new radiation oncology treatment center programs.~~

~~Assessment - Linear Accelerators~~
There are 70 hospitals and freestanding oncology treatment centers statewide in North Carolina with 114 linear accelerators that are operational, have a CON in hand, or for which there is a prior year need determination.

The utilization methodology used calls for data gathering that is uniform. There are radiation treatments of varying complexity, and the concept of ESTV is used. ESTVs are recommended by the American College of Radiology. In addition, ESTVs were recommended as part of the comments during public hearings when the original methodology was developed.

The data gathering survey that the Medical Facilities Planning Section sends out to the providers has changed the manner in which procedures are counted. This survey asks for the procedures by CPT codes and shows the equivalent ESTVs. The hospitals and free-standing centers have responded well in giving procedures that can be translated into ESTV totals.

Basic Assumptions of the Methodology
A linear accelerator's service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 27 multi-county groupings defined in Table 9G. In determining whether an additional linear accelerator is needed in a service area, three principal questions must be addressed:

1. Are the linear accelerators in ~~existing radiation oncology centers~~ a linear accelerator service area performing greater than 6,750 procedures (ESTVs) per accelerator per year?

2. Is the population that lives in a ~~radiation oncology~~ linear accelerator service area sufficiently great to support the addition of another accelerator (population per accelerator greater than 120,000 - a figure suggested by the Inter-Society Council for Radiation Oncology)?

3. Does the patient origin data show that over 45 percent of the patients come from outside the service area?

Patient origin data is requested in order to establish service areas, and the vast majority of the facilities have responded with the patient origin data.

To examine the second and third questions, ~~radiation oncology~~ linear accelerator service areas are delineated, including in each area the counties that are closest to ~~each radiation oncology program or cluster of programs. A cluster of programs is defined as all of the programs in a single county~~ a linear accelerator. Two exceptions were employed in applying this method:

a. Where patient origin data indicate a county's primary use of a ~~program~~ linear accelerator that is not the closest, the county is aligned with the ~~radiation oncology area~~ linear accelerator county where most or a plurality of its citizens go for ~~hospital care~~ linear accelerator services. Example: Alleghany to Forsyth

b. When a ~~program is one that~~ linear accelerator county has a population too small to support it, ~~the area for that program~~ that county is combined with an adjacent ~~area in which the smaller program's base county's patient origin data indicates that~~ county to which a sizable percentage of patients go for linear accelerator services, according to the base county's patient origin data. ~~to the adjacent programs.~~ Example: (Haywood - Buncombe)

Data regarding each of the ~~radiation oncology~~ linear accelerator service areas of North Carolina were organized so as to examine each of the questions noted above.

Methodology for Determining Need
The methodology incorporates a geographic accessibility criterion (population base of 120,000), a criterion aimed at assuring efficient use of megavoltage radiation facilities (when ESTV Procedures divided by 6,750 minus the number of present linear accelerators equals .25+), and a patient origin criterion (when a service area has 45 percent or more of the patients coming from outside the service area). A need determination is generated when two of the three criteria are met within a service area.
~~An additional criterion has been incorporated into the methodology based on a petition. Any county that has a population of 120,000 or more and does not have a recognized linear accelerator shall have a need for one linear accelerator and the county shall become a separate Linear Accelerator Service Area.~~

The standard methodology used for determining need for linear accelerators is calculated as follows:

Criterion 1:
Step 1. Using the 2009 NC population estimate obtained from the North Carolina Office of State Budget and Management, sum the population estimates for counties that comprise each linear accelerator service area to determine the population for linear accelerator service areas.

Step 2. For each linear accelerator service area, sum the number of operational linear accelerators acquired in accordance with G.S. 131E-175, et. seq., the number of approved linear accelerators not yet operational but for which a CON has been awarded, and the linear accelerator need determinations from previous SMFPs.

Step 3. Divide the service area population by the result of Step 2 to determine the population residing in the service area per linear accelerator. If the result is greater than or equal to 120,000 per linear accelerator, Criterion 1 is satisfied.

Criterion 2:

Step 4. Using patient origin data reported on the 2009 Hospital License Renewal Applications and Linear Accelerator Registration and Inventory Forms for linear accelerators, for each service area, count the number of patients who were served on linear accelerators located in the service area, and who reside in a county outside the service area.

Step 5. For each service area, divide the results of Step 4 by the total number of patients served on linear accelerators located in the service area. If more than 45 percent of total patients served on linear accelerators located in a service area reside outside the service area, then Criterion 2 is satisfied.

Criterion 3:

Step 6. For each linear accelerator service area, sum the number of ESTV procedures performed on the linear accelerators located in the service area as reported in each provider's 2009 Hospital License Renewal Application or Linear Accelerator Registration and Inventory Form.

Step 7. Divide the results of Step 6 by the number of linear accelerators in the service area which are counted in Step 2 to determine the average number of ESTV procedures performed per linear accelerator in each linear accelerator service area.

Step 8. Divide the results of Step 7 by 6,750 ESTV procedures.

Step 9. Subtract the number of linear accelerators in the service area counted in Step 2 from the results of Step 8. If the difference is greater than or equal to positive 0.25, Criterion 3 is satisfied.

Step 10. If any two of the above three criteria are satisfied in a linear accelerator service area, a need is determined for one additional linear accelerator in that service area.

Criterion 4:

Step 11. Regardless of the results of Steps 1-10 above, if a county has a population of 120,000 or more and there is not a linear accelerator counted in Step 2 for that county, a need is determined for one linear accelerator for that county. As a result, the county becomes a separate, new linear accelerator service area.

Linear Accelerator Need Determination

It was suggested by some radiation oncologists in 2006 that CPT Code 77427, weekly radiation therapy management, not be counted in the totals of freestanding radiation oncology centers. The advice was accepted in 2006 for the North Carolina 2007 State Medical Facilities Plan, and the procedure counts for CPT Code 77427 were removed from the totals. The

procedure counts for CPT Code 77427 also have been removed from Table 9E in this Proposed North Carolina 2010 State Medical Facilities Plan.

In the North Carolina 2008 State Medical Facilities Plan, in response to a petitioner's request for an adjustment to the need determination for linear accelerators, there was an adjusted need determination for one linear accelerator in Linear Accelerator Service Area 18. The need determination did not specify certain configurations or specifications. As Table 9F indicates, there are two service areas where the threshold equals .25+; however, there is no need determination for Service Areas 17 and 19 because these service areas do not meet the criterion of a population base of 120,000 per linear accelerator. In response to a petition, there was included in the North Carolina 2009 State Medical Facilities Plan a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men.

Through the regular need determination methodology, it is determined that there is no need for an additional linear accelerator anywhere else in the state.

Table 9F: Linear Accelerator Service Areas and Calculations

Service Area	2009 Civilian Population	Accelerators	Population within Service Area Per Accelerator	Percentage of Patients from Outside the Service Area	2007-2008 ESTV Procedures	Procedures Per Accelerator	ESTV Procedures Divided by 6750 Minus # of Accelerators	NEED Deter- mination	
Area 1	133,777	2	66,889	1.72%	6,223	3,112	-1.08		*
Area 2	390,739	7	55,820	21.32%	37,634	5,376	-1.42		*
Area 3	90,427	1	90,427	6.29%	4,005	4,005	-0.41		*
Area 4	156,733	3	52,244	12.93%	10,589	3,530	-1.43		*
Area 5	363,074	6	60,512	15.29%	21,170	3,528	-2.86		*
Area 6	442,271	5	88,454	3.07%	23,337	4,667	-1.54		*
Area 7	1,146,032	11	104,185	12.09%	58,743	5,340	-2.30		*
Area 8	297,958	4	74,490	17.03%	20,263	5,066	-1.00		*
Area 9	235,292	3	78,431	27.14%	17,558	5,853	-0.40		*
Area 10	629,269	9	69,919	27.19%	49,891	5,543	-1.61		*
Area 11	158,855	1							
Area 12	567,337	7	81,048	24.22%	41,561	5,937	-0.84		*
Area 13	141,696	1							
Area 14**	192,495	4	48,124	74.64%	22,414	5,603	-0.68		*
Area 15	170,348	2	85,174	7.08%	9,700	4,850	-0.56		*
Area 16	422,621	7	60,374	27.96%	45,784	6,541	-0.22		*
Area 17*	303,465	3	101,155	16.61%	24,467	8,156	0.62		*
Area 18	545,707	7	77,958	14.09%	30,409	4,344	-2.49		*
Area 19*	415,820	4	103,955	12.94%	34,492	8,623	1.11		*
Area 20	1,068,619	8	133,577	16.10%	42,028	5,254	-1.77		
Area 21	167,849	2	83,925	39.77%	3,706	1,853	-1.45		
Area 22	227,753	2	113,877	12.21%	12,866	6,433	-0.09		*
Area 23	186,014	3	62,005	22.27%	16,933	5,644	-0.49		*
Area 24	173,460	1							
Area 25	300,550	4	75,138	7.57%	16,552	4,138	-1.55		*
Area 26	311,418	5	62,284	3.42%	9,716	1,943	-3.56		*
Area 27	157,818	2	78,909	1.77%	7,019	3,510	-0.96		*
Totals	9,397,397	114	82,433		567,056	4,974	-29.99	0	

* Service Area does not have 120,000 base population per accelerator

** Area 14 has more than 45% of its patients coming from outside its service area

Table 9G: Linear Accelerator Service Areas

Area	County	2009 Total Population
1	Cherokee	27,958
	Clay	10,800
	Graham	8,206
	Jackson	37,731
	Macon	34,808
	Swain	14,274
	TOTAL	**133,777**
2	Buncombe	232,718
	Haywood	57,666
	Madison	20,778
	McDowell	44,709
	Mitchell	15,948
	Yancey	18,920
	TOTAL	**390,739**
3	Ashe	26,560
	Avery	18,395
	Watauga	45,472
	TOTAL	**90,427**
4	Henderson	106,214
	Polk	19,099
	Transylvania	31,420
	TOTAL	**156,733**
5	Alexander	37,372
	Burke	88,460
	Caldwell	80,052
	Catawba	157,190
	TOTAL	**363,074**
6	Rutherford	62,842
	Cleveland	97,104
	Gaston	206,538
	Lincoln	75,787
	TOTAL	**442,271**
7	Mecklenburg	919,372
	Anson	24,994
	Union	201,666
	TOTAL	**1,146,032**
8	Iredell	159,443
	Rowan	138,515
	TOTAL	**297,958**
9	Cabarrus	175,821
	Stanly	59,471
	TOTAL	**235,292**
10	Forsyth	349,449
	Davie	42,171
	Stokes	46,596
	Surry	73,876
	Wilkes	67,509
	Alleghany	11,256
	Yadkin	38,412
	TOTAL	**629,269**

Table 9G: Linear Accelerator Service Areas

Area	County		2009 Total Population
11	**Davidson**		**158,855**
12	Guilford		475,826
	Rockingham		91,511
		TOTAL	567,337
13	**Randolph**		**141,696**
14	Chatham		61,869
	Orange		130,626
		TOTAL	192,495
15	Alamance		146,889
	Caswell		23,459
		TOTAL	170,348
16	Durham		263,857
	Granville		57,127
	Person		38,145
	Vance		43,641
	Warren		19,851
		TOTAL	422,621
17	Moore		86,942
	Hoke		46,099
	Lee		58,606
	Montgomery		27,852
	Scotland		37,038
	Richmond		46,928
		TOTAL	303,465
18	Cumberland		315,955
	Bladen		32,531
	Robeson		131,368
	Sampson		65,853
		TOTAL	545,707
19	New Hanover		199,351
	Brunswick		108,419
	Columbus		54,267
	Pender		53,783
		TOTAL	415,820
20	Wake		898,818
	Franklin		58,858
	Harnett		110,943
		TOTAL	1,068,619
21	**Johnston**		**167,849**
22	Lenoir		57,255
	Duplin		54,359
	Wayne		116,139
		TOTAL	227,753
23	Craven		98,212
	Carteret		64,428
	Jones		10,411
	Pamlico		12,963
		TOTAL	186,014
24	**Onslow**		**173,460**

Table 9G: Linear Accelerator Service Areas

Area	County	2009 Total Population
25	Nash	94,723
	Edgecombe	50,748
	Northampton	21,123
	Halifax	54,684
	Wilson	79,272
	TOTAL	**300,550**
26	Pitt	158,197
	Beaufort	46,431
	Bertie	19,729
	Greene	21,353
	Hertford	23,762
	Hyde	5,325
	Martin	23,514
	Washington	13,107
	TOTAL	**311,418**
27	Pasquotank	42,753
	Camden	10,249
	Chowan	14,856
	Currituck	25,158
	Dare	34,822
	Gates	12,353
	Perquimans	13,301
	Tyrrell	4,326
	TOTAL	**157,818**

Summary of Suggestions from the 04/09/2008 Linear Accelerator Discussion Group (new items in italics)

CPT Code	CPT Code Description	Current ESTV Multiplier	Dr. Willett, Duke University	Novant 1	Novant 2	Cancer Centers of NC	SERO*
Guidance and Planning							
76950	Ultrasound Guidance	N/A				0.50	
77014	Computed tomography guidance for placement of radiation therapy fields (Cone-Beam CT)	N/A	0.75	Delete & increase treatment delivery code values	2.00	0.50	
77280-L	Simple Simulation performed on a Linear Accelerator (-L)	N/A				2.00	
77417	Additional field check radiographs	0.5	Delete here & increase treatment delivery CPT codes	Delete & increase treatment delivery code values	0.50	0.50	Delete
77421	Stereoscopic X-ray Guidance for localization of target volume for the delivery of radiation therapy	N/A		Delete & increase treatment delivery code values	1.00	0.50	
Treatment Delivery							
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS),complete course of treatment of cranial lesion(s) consisting of 1 session; multisource Cobalt 60 based (Gamma Knife)	N/A			3.00	5.00	
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session;linear accelerator	N/A	4.00 (Duke uses G0339 robotic code for SRS 1 fraction)		7.00 (Novant lists G0173 with this)	4.00	
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions **	N/A	3.00 (Duke uses G0340 robotic code for 2-5 fractions)		6.00 (imaging not included)	3.00	
G0339	(Image-guided) robotic linear accelerator-based stereotactic radiosurgery in one session or first fraction				7.00 (imaging not included)		

Summary of Suggestions from the 04/09/2008 Linear Accelerator Discussion Group (new items in italics)

CPT Code	CPT Code Description	Current ESTV Multiplier	Dr. Willett, Duke University	Novant 1	Novant 2	Cancer Centers of NC	SERO*
G0340	*(Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction*				6.00 (imaging not included)		
None Given	*Stereotactic radiotherapy (SRT) procedures, cranial or body*	N/A					3.50
	Total body irradiation	2.50		2.50	2.50		
	Hemibody irradiation	2.00		0.00	Delete	Delete	Delete
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)	10.00		10.00	10.00		Delete
	Neutron and proton radiation therapy	2.00	Delete	2.00	2.00		Delete
	Limb salvage irradiation	1.00	Delete; include with Complex Treatments	1.00	1.00	Delete	No separate designation
	Pediatric Patient under anesthesia	1.50	2.00	1.50	2.00		2.00
	Adult Patient under anesthesia			1.50	2.00		2.00
	Simple Treatment Delivery:		Delete 77417 & increase value of treatment delivery CPT codes	Delete 77417 & increase value of treatment delivery CPT codes	Keep 77417 at 0.50 and treatment delivery codes at 1.00		
77401	Radiation treatment delivery	1.00	1.20	1.25	1.00		1.15
77402	Radiation treatment delivery (<=5 MeV)	1.00	1.20	1.25	1.00		1.15
77403	Radiation treatment delivery (6-10 MeV)	1.00	1.20	1.25	1.00	1.00	1.15
77404	Radiation treatment delivery (11-19 MeV)	1.00	1.20	1.25	1.00	1.00	1.15
77406	Radiation treatment delivery (>=20 MeV)	1.00	1.20	1.25	1.00	1.00	1.15
	Intermediate Treatment Delivery:		Delete 77417 & increase value of treatment delivery CPT codes	Delete 77417 & increase value of treatment delivery CPT codes	Keep 77417 at 0.50 and treatment delivery codes at 1.00		
77407	Radiation treatment delivery (<=5 MeV)	1.00	1.40	1.25	1.00	1.00	1.15

Summary of Suggestions from the 04/09/2008 Linear Accelerator Discussion Group (new items in italics)

CPT Code	CPT Code Description	Current ESTV Multiplier	Dr. Willett, Duke University	Novant 1	Novant 2	Cancer Centers of NC	SERO*
77408	Radiation treatment delivery (6-10 MeV)	1.00	1.40	1.25	1.00	1.00	1.15
77409	Radiation treatment delivery (11-19 MeV)	1.00	1.40	1.25	1.00	1.00	1.15
77411	Radiation treatment delivery (>=20 MeV)	1.00	1.40	1.25	1.00	1.00	1.15
	Complex Treatment Delivery:		Delete 77417 & increase value of treatment delivery CPT codes	Delete 77417 & increase value of treatment delivery CPT codes	Keep 77417 at 0.50 and treatment delivery codes at 1.00		
77412	Radiation treatment delivery (<=5 MeV)	1.00	1.60	1.25	1.00	1.00	1.15
77413	Radiation treatment delivery (6-10 MeV)	1.00	1.60	1.25	1.00	1.00	1.15
77414	Radiation treatment delivery (11-19 MeV)	1.00	1.60	1.25	1.00	1.00	1.15
77416	Radiation treatment delivery (>= 20 MeV)	1.00	1.60	1.25	1.00	1.00	1.15
77418	Intensity modulated radiation treatment (IMRT) delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session	1.00	2.00	CPT 77421 or 77014 not listed separately, increase value of 77418 to 1.50	Have 77421 at 1.00 & 77014 at 2.00, and 77418 at 1.25	2.00	1.50
Treatment/Therapy Management							
77427	Weekly radiation therapy management	Procedures not counted				Delete	
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session) Linear Accelerator	3.00		CPT 77421 or 77014 included in treatment delivery CPT codes 3.50		Delete	5.50
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session) Gamma Knife	3.00		3.00		Delete	5.50

* SERO Proposal also included: (1) Reduce the population standard from 120,000 per linac to 108,000 people per linac; and (2) Create an equivalent linac with the following formula: $0.4 + 0.6 \times (1.00 - [(\#SRS \times 5.5 + \#SRT \times 3.5) / (\#SRS \times 5.5 + \#SRT \times 3.5 + \#XRT \times 1.15)])$.

** 77373 (Do not report 77373 in conjunction with 77401-77416,77418)