Technology and Equipment Committee Meeting

Magnetic Resonance Imaging (MRI) Material

April 29, 2009

Magnetic Resonance Imaging

Introduction

Magnetic Resonance Imaging (MRI) technology is mobile and apparently is financially feasible at relatively small-volume mobile sites. Geographic accessibility is a significant planning issue, and it is important to assure that the rural areas of the State have the opportunity to access this important technology through both fixed and mobile scanners, as it has become the standard of care.

The methodology that is used allows the addition of a fixed MRI scanner at a fixed site within the same MRI service area.

The Technology

Nuclei of atoms in various structures of the human body resonate differentially when exposed to a strong magnetic field. MRI devices register these differences in response as images for use in making diagnoses. Use of MRI technology has grown rapidly because it does not expose patients to ionizing radiation, and because of the quality of images it obtains. In 1983, there were only two MRI programs in North Carolina, performing a total of 531 procedures. In 2007-08, fixed and mobile scanners were reported as providing _____ procedures.

An MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

An MRI procedure is a single MRI procedure performed on one defined body part during one visit. Each MRI procedure must be directly linked to a single billable CPT code associated with an MRI procedure. For example, an MRI brain scan with and without contrast is a single procedure, with a single CPT code.

For reporting verification, each reporting site will provide the number of scans performed annually for all CPT codes by volume on Hospital License Renewal Applications and Registration and Inventory of Medical Equipment Forms for Fixed (Non-Hospital) and Mobile MRI Providers.

Assessment

MOBILE MRI

Because of the availability of mobile units, it appears that MRI technology is accessible within a reasonable distance and travel time to all of the population of North Carolina. Several mobile sites in operation all of 2007-08 reported less than 200 procedures.

Mobile MRI scanner means an MRI scanner and transporting equipment that is moved at least weekly to provide services at two or more host facilities.

Some sites that initiated MRI service with mobile units have installed fixed scanners as volumes increased. Because of the need to house a unit in a specially constructed building or area of a building, the cost of each such new fixed facility may exceed \$2,000,000.

FIXED MRI UNITS

Fixed MRI scanner means an MRI scanner that is not a mobile MRI scanner. The principal capital expenditure issue with respect to fixed MRI units is the volume of procedures, which warrants the acquisition of an additional magnet.

Definition of an MRI Service Area

An fixed MRI Service Area is the same as an Acute Care Service Area as defined in Chapter 5, Acute Care Beds, and contained in Figure 5.1. The fixed MRI Service Area is a single county, except where there is no hospital located within the county, in which case, the county or counties without a hospital are combined in a multi-county grouping with a county that has a hospital. Multi-county groupings are determined based on the county in which the hospital or hospitals are located that provide the largest number of inpatient days of care to the residents of the county that has no hospital. An fixed MRI scanner's service area is the MRI service area in which the scanner is located.

Basic Assumptions of the Methodology

- 1. Facilities that currently offer mobile MRI services, but have received the transmittal of a CON for a fixed MRI scanner are included in the inventory as a fixed MRI scanner in Table 9K.
- 2. A placeholder of one MRI scanner is placed in Table 9K for each new fixed MRI scanner for which a CON has been issued even if the scanner is not operational. All procedures performed by a single licensed entity are counted as performed at a single site, even if MRI services are provided at more than one site.
- 3. The need determination for any one Service Area under the methodology for Fixed MRI Scanner Utilization shall not exceed one MRI scanner per year, unless there is an adjusted need determination approved for a specific MRI Service Area.
- 4. A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination in the <u>North Carolina 2010 State Medical Facilities Plan</u> to replace the existing contracted service with a fixed MRI scanner under the applicant's ownership and control. It is consistent with the purposes of the CON law and the State Medical Facilities Plan for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility's own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility.

Methodology for Determining Need

The methodology includes need thresholds arranged in tiers based on the number of scanners, weighting of procedures based on complexity, and a component addressing MRI service areas that have no fixed MRIs, but have mobile MRI scanners serving the area. The methodology for determining need is based on fixed and mobile procedures performed at hospitals and freestanding facilities with fixed MRI scanners and procedures performed on mobile MRI scanners at mobile sites in the MRI service areas. In addition, equivalent values for mobile scanners in MRI service areas are found in the column labeled Fixed Equivalent Magnets in Table 9K.

Acute Care Service Area Fixed Scanners	Inpatient and Contrast Adjusted Thresholds	Planning Threshold
4 and over	4,805 ¹	70.0%
3	$4,462^{2}$	65.0%
2	4,118 ³	60.0%
1	3,775 ⁴	55.0%
0	1,716 ⁵	25.0%

MRI Tiered Planning Thresholds

The above tiering is based on the assumption that the time necessary to complete 1.0 MRI procedure (a basic outpatient procedure without contrast) is 30 minutes, or an average throughput of two procedures per hour on an MRI scanner. Capacity of a single MRI scanner is defined as that of an MRI scanner being available and staffed for use at least 66 hours per week, and 52 weeks per year. The resulting capacity of a fixed MRI scanner is defined below:

Annual Maximum Capacity of a Single Fixed MRI Scanner = 66 hours per week x 52 weeks x 2 procedures per hour = 6,864 procedures annually

This definition of capacity represents 100% of the procedure volume the equipment is capable of completing, given perfect scheduling, no machine or room downtime, no cancellations, no patient transportation problems, no staffing or physician delays and no MRI procedures outside the norm.

Procedure totals are from the 2009 Hospital Licensure Renewal Application or the 2009 MRI Registration and Inventory of Medical Equipment Form as submitted to the North Carolina Division of Health Service Regulation concerning equipment registration and inventory, and number of procedures.

 $^{^{1}}$ 6,864 X 70% = 4,805

 $^{^{2}}$ 6,864 X 65% = 4,462

 $^{^{3}}$ 6,864 X 60% = 4,118

 $^{^{4}}_{5}$ 6,864 X 55% = 3,775

 $^{^{5}}$ 6,864 X 25% = 1,716

				PROCEDURE
PROCEDURE	BASE	INPATIENT	CONTRAST	TIME
TYPE	WEIGHT	WEIGHT	WEIGHT	MINUTES
Outpatient/No	1.0	0.0	0.0	30
Contrast/Sedation				
Outpatient/With	1.0	0.0	.4 (Add 12	42
Contrast/Sedation			minutes)	
Inpatient/No	1.0	.4 (Add 12	0.0	42
Contrast/Sedation		minutes)		
Inpatient/With	1.0	.4 (Add 12	.4 (Add 12	54
Contrast/Sedation		minutes)	minutes)	

The table below indicates the weighting values assigned to the procedure type:

Procedures with contrast include those with sedation as reported in the annual Hospital Licensure Renewal Application and the annual Registration and Inventory of Medical Equipment for Fixed and Mobile MRIs.

Need Determination

Weighting System

The standard methodology used to determine need for fixed MRI scanners is calculated as follows:

Step 1. Determine the number of clinical fixed and mobile MRI scanners in each MRI service area by site to include: existing fixed or mobile MRI scanners in operation, approved fixed or mobile MRI scanners for which a CON was issued but is pending development, and fixed MRI scanners for which no CON has been issued because the decision regarding a need determination in a previous SMFP is under review or appeal. The inventory shall exclude: MRI scanners used for research only, non-clinical MRI scanners, and MRI scanners awarded based on need determinations for a dedicated purpose or demonstration project.

Step 2. Convert the number of fixed and mobile MRI scanners to fixed equivalent magnets as follows:

(a) For each existing fixed MRI scanner assign a value of one fixed equivalent magnet;

(b) For each approved fixed MRI scanner assign a value of one fixed equivalent magnet, even though the site may be receiving mobile services temporarily until the fixed scanner is operational. [Note: The mobile services are not listed separately from the approved fixed MRI scanner if the mobile unit will no longer be used when the fixed MRI scanner is operational.]

(c) for each existing mobile MRI scanner site calculate the fixed equivalent for each mobile site by dividing the number of MRI scans performed at each site by the threshold for the MRI service area, with the exception that the fixed equivalent shall be no greater than one; and

(d) for each approved mobile MRI scanner site, at which services have not started, calculate the days to be operated at the site as a fraction of the total days of service to be provided by the approved mobile MRI scanner. [For example, if a CON has been awarded to a provider to serve six different sites in the State for one day per week at each site, the fixed equivalent for each approved site in the State is 0.17 (1/6=.1666). If the mobile is approved to serve two sites for three days per week at each site the fixed equivalent for each site is 0.50 (3/6=.50).]

Step 3. Sum the number of fixed equivalent magnets for each MRI service area.

Step 4. Determine the total number of MRI scans performed at each site regardless of whether the MRI scanner is fixed or mobile, as reported in the 2009 Hospital License Renewal Applications or 2009 MRI Registration and Inventory Forms.

Step 5. Of the total number of MRI scans performed, determine the number of MRI scans performed by type (i.e. inpatient, outpatient, with contrast or sedation, no contrast or sedation) as reported in the 2009 Hospital License Renewal Applications or 2009 MRI Registration and Inventory Forms.

Step 6. For each site, multiply the number of inpatient MRI scans by 0.40 to calculate the inpatient adjustment.

Step 7. For each site, multiply the number of contrast or sedation scans by 0.40 to calculate the contrast adjustment.

Step 8. For each site, sum the total number of MRI scans performed (Step 3), the inpatient adjustment (Step 5), and the contrast adjustment (Step 6) to calculate the total number of adjusted MRI procedures for each site.

Step 9. For each service area, sum the number of adjusted total MRI procedures for all sites in the MRI service area.

Step 10. Calculate the average number of adjusted total MRI procedures per MRI scanner in the service area by dividing the adjusted total procedures for the service area (Step 9) by the sum of fixed equivalent magnets in the service area (Step 3).

Step 11. Determine the utilization threshold for the service area based only on the number of existing, approved and pending fixed MRI scanners located in the service area as identified in Step 1:

- 4+ fixed MRI scanners 4,805 threshold
- 3 fixed MRI scanners 4,462 threshold
- 2 fixed MRI scanners 4,118 threshold
- 1 fixed MRI scanner 3,775 threshold
- 0 fixed MRI scanners 1,716 threshold

Step 12. Compare the area average procedures per fixed equivalent magnet (Step 10) with the threshold for the MRI service area (Step 11). If the area average procedure per magnet is greater than or equal to the service area threshold, a need is determined for one additional MRI scanner in the service area.

The tables reflect the MRI service areas. There is a need in Table 9K for an additional fixed MRI scanner in ______. There is no need for any additional fixed MRI scanners anywhere else in the state.

Tables

The following tables are included in this section of the chapter: Table 9K, MRI Procedures by MRI Service Areas – All Fixed and Mobile Procedures – TOTALS with Tiered & % Mobile Equivalents; Table 9L (1), Inventory of MRI Scanners for Cardiovascular Clinical Research Use Pursuant to Policy AC-3 in the 2001 SMFP; Table 9L (2), Inventory of Dedicated Breast MRI Scanners Pursuant to Adjusted Need Determination in the 2002 and 2006 SMFPs; Table 9L (3) Inventory of Dedicated Pediatric MRI Scanner Pursuant to Adjusted Need Determination in the 2005 SMFP; Table 9L (4) Inventory of Demonstration Project for a Fixed Extremity MRI Scanner Pursuant to Adjusted Need Determination in the 2006 SMFP; Table 9L (5), Inventory of MRI Scanners Dedicated for Radiation Oncology and Use in Operating Room Suite; Table 9L (6): Inventory of Fixed Multi-Position MRI Scanners Dedicated For Two Demonstration Projects; and Table 9M, Fixed MRI Scanners Need Determination.