



PETITION

Petition to Change Policy TE-2 to Allow iMRI Use for Outpatients

PETITIONER

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INTRODUCTION

Atrium Health (Atrium) appreciates the opportunity to comment on the *Proposed 2024 State Medical Facilities Plan (SMFP)*. Atrium is requesting the State Health Coordinating Council (SHCC) consider a minor revision in language included in Policy TE-2 related to the use of intraoperative MRI (iMRI) scanners for outpatients. Since the policy was adopted several years ago there have been changes in the field of medicine with new outpatient procedures developed that benefit from using intraoperative MRI technology. Based on the information provided below, Atrium requests the SHCC make minor revisions to Policy TE-2.

BACKGROUND ON POLICY TE-2

The history of Policy TE-2 dates back to 2015. In March of 2015 Carolinas HealthCare System (now Atrium Health) filed a petition to add a need for an intraoperative MRI scanner for the western part of the state (HSA I, II and III). The Technology and Equipment Committee (TEC) voted to deny the petition but alternatively proposed the adoption of Policy TE-2. The SHCC agreed and the policy was added to the 2016 SMFP. Carolinas Medical Center (CMC) filed a CON application and was approved to develop an iMRI scanner in an operating room. The iMRI scanner has been in operation since 2019.

Although it is not reflected in the SHCC or TEC minutes, there was some discussion in the meetings on the potential to use the iMRI to scan inpatients, even if there were no surgical procedure needed by the patient. The SHCC and the CON Chief agreed to allow the iMRI to be used for diagnostic MRI scans for inpatients. All parties agreed the iMRI scanner was not to be used for outpatient diagnostic MRI scans as a circumvention of the standard MRI methodology. The following language was ultimately included in the policy:

“The iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.”

At the time, Atrium fully agreed with the prohibition of using the iMRI for outpatients because the primary use was intended for neurosurgical patients who would be inpatients. In fact, Atrium installed the iMRI in a renovated operating room in the surgical suite which made it inaccessible to traditional outpatient diagnostic MRI patients.

PROPOSED CHANGE TO POLICY TE-2

Atrium requests the SHCC make a slight modification to the language in Policy TE-2 which prevents the use of an iMRI for all outpatients. Atrium believes the spirit of the restriction was intended only for outpatients who do not have a procedure at the time of the iMRI scan. Atrium proposes the following revised language to replace the sentence below the numbered list of criteria in Policy TE-2.

The iMRI scanner shall not be used for outpatients unless the patient has a simultaneous surgical procedure, interventional procedure or treatment. The iMRI scanner may not be replaced with a conventional MRI scanner.

IMPACT OF THE PROPOSED CHANGE TO POLICY TE-2

As previously described, the limitation of the current policy to inpatients was based on the primary expected use for neurosurgical patients. There were also concerns raised that use of the equipment for outpatients without a simultaneous procedure would circumvent the MRI need determinations in the SMFP. The proposed change will allow providers with an iMRI to use the equipment for new types of procedures that have been and will continue to be developed that can be done on an outpatient basis. The proposed change will still limit the use of iMRI scanners for outpatients that do not have a simultaneous procedure or interventional treatment.

REASON FOR THE PROPOSED CHANGE IN POLICY TE-2

In 2015, neurosurgical procedures were the most common application of iMRI services, and all patients were admitted to the hospital for recovery. Since that time there have been advances in the application of the iMRI technology for new treatments (other than neurosurgery) that can be provided on an outpatient basis. One example of an outpatient procedure is the TULSA procedure for prostate cancer. TULSA stands for ***Transurethral Ultrasound Ablation***. These procedures are done in an MRI suite and typically take 3-4 hours to complete. Due to the duration of the treatment, most locations offering this procedure use an iMRI to minimize the impact on traditional MRI scanners.

Atrium has already contacted Michaela Mitchell, Chief of Healthcare Planning and Certificate of Need, regarding a material compliance approval to do these outpatient procedures on the iMRI. Based on the language in the SMFP policy preventing use on outpatients, which was also included as a condition on the CON, the CON Section was not able to grant approval to do outpatient procedures on the iMRI. The

requested change in the policy language is the only pathway to expand usage of the iMRI for outpatients who need a procedure and intraoperative MRI scans.

ADVERSE EFFECTS IF THE PETITION IS NOT APPROVED

The language of Policy TE-3 has remained unchanged since it was first adopted in the 2016 SMFP. Medical science is constantly innovating and developing new procedures and technology to benefit patients. If the proposed change is not approved the advanced technology of iMRI scanners will not be able to be used for the full range of procedures and diseases that could be treated with the technology. These extremely expensive pieces of equipment will not be used to help the full universe of patients. This limitation will reduce the efficiency and cost effectiveness of care provided.

ALTERNATIVES CONSIDERED TO THE PROPOSED CHANGE

The only alternative to the proposed change is the status quo which does not allow providers to use an iMRI scanner on any outpatients.

UNNECESSARY DUPLICATION

The proposed change in the policy would not result in unnecessary duplication of health resources. The use of the iMRI for outpatients will expand utilization of the equipment for procedures that are not currently being performed. There will be no duplication of services or expansion in the number of iMRI scanners because of this petition.

CONSISTENCY WITH BASIC PRINCIPLES

Atrium believes the petition is consistent with the three basic principles: safety and quality, access, and value.

Safety and Quality

The iMRI has already improved the safety and quality of care provided to our patients by reducing the need for added neurosurgical procedures to remove tumors. The iMRI has allowed neurosurgeons to determine if tumors have been completely removed during the surgery with the iMRI scan in the operating room. Prior to installing the iMRI these patients would have received an MRI scan after surgery was completed and if more tumor resection was required the patient would receive a second operation. The expansion of iMRI use to allow outpatients will offer the same benefit to a larger segment of the patient population.

Access

The requested change to allow outpatient use of iMRI equipment will increase access to the technology for more patients in a broader range of specialties. As medical science and technology advance there will undoubtedly be more applications for the iMRI technology that can be used for outpatients. The

TULSA procedure listed above is just one example. The proposed change to Policy TE-2 will expand the application of iMRI technology to a broader population of patients.

Value

The ability to use iMRI scanners for outpatients will meet the value principle by allowing access to the technology for a lower cost than inpatient care. Inpatient care is more costly for patients, insurers and employers than outpatient care. Allowing iMRI use for outpatients will increase the value of care for patients treated with this technology.

CONCLUSION

Atrium appreciates the work of the SHCC and the Healthcare Planning and Certificate of Need Section staff in preparing the SMFP each year. Thank you for your consideration of our request to expand the use of iMRI services.