



September 20, 2002

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Mr. Norris,

We are writing to you in regards to the national coverage of  $^{13}\text{NH}_3$  (Ammonia) for PET myocardial perfusion imaging. As you know, currently  $^{82}\text{Rb}$  (Rubidium) is the only isotope CMS will reimburse for PET myocardial perfusion imaging. However, it has been shown throughout the literature that using  $^{13}\text{NH}_3$  for PET myocardial perfusion imaging is at least equal to if not superior to  $^{82}\text{Rb}$  for this exam.

In 1994, the manufacturer of  $^{82}\text{Rb}$  was successful in convincing HCFA to allow for Medicare reimbursement for PET myocardial perfusion imaging. However, since  $^{13}\text{NH}_3$  is produced on a cyclotron instead of a generator, there was no one manufacturer or source lobbying HCFA to convince them that  $^{13}\text{NH}_3$  should be reimbursed as well. For those of us in the PET community that have invested in a medical cyclotron (at a cost of over \$2 million), we are caught in a financial hardship. It is cost prohibitive to purchase and operate a cyclotron as well as purchase a  $^{82}\text{Rb}$  generator at a cost of over \$30,000 per month. While we feel there is a need to perform PET myocardial perfusion imaging, physicians at our institution are reluctant to utilize the procedure because many of their patients are Medicare recipients.

From a physics standpoint,  $^{13}\text{NH}_3$  is a superior imaging agent to  $^{82}\text{Rb}$  because it provides a higher resolution image than  $^{82}\text{Rb}$ . This is because the maximum positron range in tissue for  $^{13}\text{NH}_3$  is 3.0mm whereas the maximum positron range in tissue for  $^{82}\text{Rb}$  is 16.5mm. This means that the  $^{13}\text{NH}_3$  positron moves only 3.0mm (1) before it annihilates but the  $^{82}\text{Rb}$  positron moves 16.5mm (2) before it annihilates (this annihilation reaction produces two 511KeV gamma rays 1800 apart and this is what the PET scanner "sees"). This leads to a much higher resolution image. Therefore, if CMS is currently reimbursing Medicare recipients for PET myocardial perfusion imaging while  $^{82}\text{Rb}$  is being used, it should also reimburse them for  $^{13}\text{NH}_3$  since it is a superior imaging agent than  $^{82}\text{Rb}$ .

In 2000, we met with our local Medicare Medical Director, S. Satya-Murti in Topeka, Kansas and he understood our rationale for needing reimbursement for  $^{13}\text{NH}_3$ , but he said

there was nothing he could do because he had to follow the national policy set forth by HCFA.

In addition, as you know, the FDA has reviewed the use of  $^{13}\text{NH}_3$  for the evaluation of PET myocardial perfusion imaging and has found it to be safe and effective to use. Since we have only done a few  $^{13}\text{NH}_3$  myocardial perfusion imaging studies, we cannot provide data from our own experience. Instead, we are supporting the use of  $^{13}\text{NH}_3$  for myocardial perfusion imaging because it has superior characteristics from a physics standpoint and because it would allow us to provide our patients with this important imaging procedure.

Thank you for your time and consideration,



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