Your presentation must address the following questions being asked by CMS to the Committee and the issues discussed in the technology assessment. If the specific questions are not addressed your presentation will not be accepted. An electronic copy must be submitted to the Executive Secretary Michelle Atkinson (matkinson@cms.hhs.gov) no later than July 7, 2004, 5:00pm, E.D.T. The presentation that you submit on July 7 will be the final presentation given to the Committee members. There will be no modifications or additional information accepted after July 7 or on the day of the MCAC meeting. We also require that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

Question #2 includes the term "validity." CMS uses "validity" here as defined by Meinert, "Validity, in the context of a treatment difference, refers to the extent to which that difference can be reasonably attributed to a treatment assignment." (Meinert CL. Clinical Trials, Overview. In: Redmond CK, Colton T, eds. Biostatistics in clinical trials. Wiley and Sons, 2001. pp. 37-51). This encompasses all issues of methodologic framework, study design, observed results, biological rationale, etc.

Question #2 refers to 'Short Term Mortality." CMS defines that up to 30 days after the procedure.

Question #3 refers to "net health benefit." CMS defines that as the balance between risks and benefits.

Medicare Coverage Advisory Committee – TMR Evaluative Questions

1. How well does the evidence address the effectiveness of TMR in the treatment of chronic, refractory angina in study patients for whom other methods of revascularization are contraindicated?

O	O	O	O	**X**
Limited		Moderate		Complete

2.

	How confident are you in the validity of the scientific data for this outcome? (no confidence = 1; moderate confidence =3; high confidence = 5)	How likely is it that TMR will improve this outcome (compared to Usual Care)? (not likely = 1; reasonably likely = 3; very likely = 5)
Short-Term Mortality	5	1
Long-Term Survival	3	4
Morbidity	5	4
Quality of Life	5	5

3. How confident are you that TMR will produce a clinically important net health benefit in the treatment of chronic, refractory angina in study patients for whom other methods of revascularization are contraindicated?

O	O	O	O	**X**
No Confidence		Moderate Confidence		High Confidence

4. Based on the literature presented, how likely is it that the results of TMR in the treatment of chronic, medically refractory angina can be generalized to:

<u>The Medicare population (aged 65+):</u>

O	O	O	O	**X**
Not likely		Reasonably Likely		Very Likely

<u>Providers (facilities/physicians) in community practice:</u>

O	O	O	**X**	O
Not likely		Reasonably Likely		Very Likely

Medicare Coverage Advisory Committee – TMR+CABG Evaluative Questions

1. How well does the evidence address the effectiveness of TMR + CABG in the treatment of chronic, refractory angina in study patients for whom other methods of revascularization are contraindicated?

O	O	**X**	O	O
Limited		Moderate		Complete

2.

	How confident are you in the validity of the scientific data for this outcome? (no confidence = 1; moderate confidence =3; high confidence = 5)	How likely is it that TMR+CABG will improve this outcome (compared to Usual Care)? (not likely = 1; reasonably likely = 3; very likely = 5)
Short-Term Mortality	3	2
Long-Term Survival	3	2
Morbidity	3	3
Quality of Life	3	4

3. How confident are you that TMR + CABG will produce a clinically important net health benefit in the treatment of chronic, refractory angina in study patients for whom other methods of revascularization are contraindicated?

O	O	**X**	O	O
No Confidence		Moderate Confidence		High Confidence

4. Based on the literature presented, how likely is it that the results of TMR+CABG in the treatment of chronic, medically refractory angina can be generalized to:

<u>The Medicare population (aged 65+):</u>

O	O	O	O	**X**
Not likely		Reasonably Likely		Very Likely

<u>Providers (facilities/physicians) in community practice:</u>

O	O	O	**X**	O
Not likely		Reasonably Likely		Very Likely

Medicare Coverage Advisory Committee – PMR Evaluative Questions

1. How well does the evidence address the effectiveness of PMR in the treatment of chronic, refractory angina in study patients for whom other methods of revascularization are contraindicated?

O	O	O	O	O
Limited		Moderate		Complete

2.

	How confident are you in the validity of the scientific data for this outcome? (no confidence = 1; moderate confidence =3; high confidence = 5)	How likely is it that PMR will improve this outcome (compared to Usual Care)? (not likely = 1; reasonably likely = 3; very likely = 5)
Short-Term Mortality		
Long-Term Survival		
Morbidity		
Quality of Life		

3. How confident are you that PMR will produce a clinically important net health benefit in the treatment of chronic, refractory angina in study patients for whom other methods of revascularization are contraindicated?

O	O	O	O	O
No Confidence		Moderate Confidence		High Confidence

4. Based on the literature presented, how likely is it that the results of PMR in the treatment of chronic, medically refractory angina can be generalized to:

<u>The Medicare population (aged 65+):</u>

O	O	O	O	O
Not likely		Reasonably Likely		Very Likely

<u>Providers (facilities/physicians) in community practice:</u>

O	O	O	O	O
Not likely		Reasonably Likely		Very Likely