

March 22, 2017 MEDCAC Voting Scores
Health Outcomes in Heart Failure Treatment Technology Studies

For the voting questions, use the following scale identifying level of confidence - with 1 being the lowest or no confidence and 5 representing a high level of confidence.		Hirsch	Cruz-Flores	Fisch	Kobylarz	Salive	Sedrakyan	Segal	Swain	Zuckerman	Hsich	Stevenson	Renbaum	Berliner	Desvigne-Nickens	Yancy	Zuckerman	Voting Member Average	Overall Average
1	How confident are you that the following are standalone, meaningful primary health outcomes in research studies of heart failure treatment technologies:																		
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>																		
	a. Heart failure hospitalization;	3	3	2	4	3	3	2	1	1	3	4	3	2	3	5	4	2.44	2.88
	b. Heart failure hospitalization or heart failure hospitalization equivalent events (e.g., outpatient IV therapy for heart failure);	3	4	3	4	3	3	3	1	1	3	4	4	2	3	3	4	2.78	3.00
	c. Total Hospitalizations?	2	2	4	3	2	2	2	1	1	3	5	3	2	2	4	3	2.11	2.56

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2	How confident are you that surrogate and intermediate endpoints (e.g., reduction in mitral regurgitation, cardiac remodeling, ejection fraction, or biomarkers) are predictive of standalone, meaningful primary health outcomes in clinical research studies of heart failure treatment technologies for:																		
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>																		
	a. Heart failure with preserved ejection fraction;	1	2	1	3	1	2	2	1	1	1	1	2	1	1	2	2	1.56	1.50
	b. Heart failure secondary to degenerative mitral regurgitation where the focus of therapy is mitral valve repair/ replacement;	1	2	1	2	2	2	4	1	1	2	1	2	1	1	4	3	1.78	1.88
	c. Heart failure secondary to functional mitral regurgitation where the focus of therapy is mitral valve repair/ replacement;	2	1	1	3	1	2	3	1	1	1	3	4	1	2	2	3	1.67	1.94
	d. Heart failure with reduced ejection fraction (e.g., cardiac remodeling, ejection fraction)?	3	2	3	3	2	2	4	1	1	3	3	3	1	3	5	4	2.33	2.69

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3	How confident are you that quality of life measures [e.g., Kansas City Cardiomyopathy Questionnaire (KCCQ), Minnesota Living With Heart Failure Questionnaire (MLWHFQ)]:																		
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>																		
	a. Are adequate measures which reflect the patient experience;	4	4	4	4	5	4	5	2	2	5	5	5	4	4	3	3	3.78	3.94
	b. Should be a standalone, meaningful primary health outcomes in research studies;	4	4	3	2	4	2	3	1	3	3	3	4	3	1	3	3	2.89	2.88
	c. Should be included as a composite, meaningful primary health outcomes in research studies?	3	4	2	4	5	4	5	2	1	4	5	4	4	5	5	4	3.33	3.81

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4	How confident are you that functional assessments [e.g., 6 min walk test (6MWT), VO2max, ventilatory threshold]:																		
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>																		
	a. Are adequate measures which reflect the patient experience;	4	3	3	3	5	3	4	3	1	5	4	4	3	4	3	4	3.22	3.50
	b. Should be a standalone, meaningful primary health outcomes in research studies;	2	3	1	3	4	2	3	3	1	2	3	3	1	2	1	3	2.44	2.31
	c. Should be included as a composite, meaningful primary health outcomes in research studies?	4	4	2	3	2	4	3	3	1	4	4	4	1	2	4	4	2.89	3.06