

**Chimeric Antigen Receptor (CAR) T-Cell Therapy and
Patient Reported Outcomes
August 22, 2018 MEDCAC Voting Scores**

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.		Cuyjet	Cheng	Civic	Frankel	Garrido	Goss	James, III	Lamon	Perissinotto	Feinglass	Gottschalk	Olson	Yang	Voting Member Average	Overall Average
1	How confident are you that each of the following PRO assessments are valid and generalizable to the Medicare population?															
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>															
a.	Patient-Reported Outcomes-Common Terminology Criteria for Adverse Events (PRO-CTCAE);	3	4	4	3	3	3	4	4	4	3	4	4	3	3.56	3.54
b.	MD Anderson Symptom Inventory (MDASI);	4	3	3	3	3	4	4	4	3	3	3	4	4	3.44	3.46
c.	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC—QLQ-C30 (core questionnaire);	3	4	4	3	4	5	5	4	4	4	4	4	4	4.00	4.00
d.	University of Washington Quality of Life (UW-QOL);	2	2	2	1	1	1	2	2	1	2	2	2	1	1.56	1.62
e.	Patient-Reported Outcome Measurement Information System (PROMIS);	4	5	4	5	4	3	5	4	5	3	4	4	4	4.33	4.15
f.	Electronic Self-Report—Cancer (ESRA-C);	2	2	1	1	1	2	2	2	2	1	2	1	1	1.67	1.54
g.	Functional Living Index—Cancer (FLIC).	2	2	1	1	1	2	1	2	1	1	1	1	2	1.44	1.38

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2	Considering all PRO assessments in question 1 with greater than or equal to score 2.5, please vote whether or not those PRO assessments combined have available supporting evidence on each of the following desired characteristics.													
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>													
	Characteristics	Tools (Yes/No)												
A.	Breadth of measures in emotional, social, and physical well-being	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
B.	Quick throughput to apply to clinical study	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
C.	Transferable to community practice settings	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
D.	Measures are not sensitive to differences in age	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	NO	YES	NO
E.	Measures are not sensitive to line of therapy	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	NO	NO	NO
F.	Measures are not sensitive to comorbidities	YES	NO	NO	YES	YES	YES	YES	YES	YES	YES	NO	YES	NO
G.	Measures are generalizable to study of combinations of therapies	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
H.	Used in net benefit analysis based on symptom burden and well-being	YES	YES	NO	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES

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3	How confident are you that each of the following assessment intervals are appropriate measurement periods for a valid PRO assessment?															
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>															
a.	Variable event-dependent frequency interval (i.e. upon admission and after discharge)	1	3	3	3	3	1	3	1	1	1	2	3	4	2.11	2.23
b.	Fixed time-dependent frequency interval (i.e. weekly, monthly, or yearly)	4	4	4	4	3	4	3	5	5	4	4	4	2	4.00	3.85

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4	How confident are you that a PRO assessment over the course of the following study durations identifies a meaningful durable treatment effect with a valid PRO?															
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>															
a.	6 months	2	2	2	2	3	2	2	1	2	2	2	3	3	2.00	2.15
b.	12 months	3	4	3	3	2	3	4	4	4	3	3	4	4	3.33	3.38
c.	24 months	5	5	3	4	1	4	5	5	5	3	4	4	5	4.11	4.08

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5	How confident are you that PRO assessments can provide meaningful results when studied with each of the following control populations?															
	<i>1 Low Confidence -2- 3 Intermediate Confidence -4- 5 High Confidence</i>															
a.	Patient him/herself, before and after intervention	4	4	3	3	3	4	3	5	5	4	4	5	3	3.78	3.85
b.	Usual care versus protocol-driven intervention	4	4	4	4	3	4	4	5	3	3	4	3	5	3.89	3.85
c.	Historical control	1	2	2	4	2	3	2	1	1	1	1	3	1	2.00	1.85