## ASCO Value Framework Advanced Disease MM

ASCO Value Framework for Advanced Disease: Ninlaro: relapsed multiple myeloma patients who have received at least one prior treatment; 2.3, 3, 4 mg capsules three times per month

Step 1: Determin					oo oh our-	holow	ond	ultiply by 40	104-	to this -	umbor in th	a hav laboled "OC	08
1A) Is <u>Overall</u> Survival (OS) reported?	Score." Pro			hrough 5	as shown		and m			te this n		e box labeled "OS	OS Score
reported?	OS Score				1	2		3	4		5		
	Improveme change in m			%	>0%-24%	% 25%	5–49%	9% 50%-75%		6–100%	At double the median OS of the new regimen, there is a 50% improvement in the fraction of patients surviving		
	NO. Procee	ed to 1	в.										
<b>1B)</b> If OS is not reported, is	YES. Assig Score." Pro			through 5	as shown	below)	and m	nultiply by 11	I. Wri	ite this n	umber in th	e box labeled "PFS	PFS Score
Progression- Free Survival	PFS Score				1	2		3	4		5		
(PFS) reported? NRD vs. RD 20.6 vs. 14.7 mo =40%		Improvement in median PFS (% change in median PFS)			>0%-24%	% 25%	5-49%	50%-75%	76%	6–100%	At double the median PFS of the new regimen, there is a 50% improvement in the fraction of patients w/o progression or death		22
-40%	NO. Proce	ed to 1	с										
1C) If neither OS nor PFS is reported, is		sponse						nultiply by 8. this numbe				d by adding the Score."	RR Score
Response Rate (RR) reported?	RR Score				1	2		3	4		5		
(ITT) reported :	What was to (CR + PR)?		rted respor	nse rate	>0%-20%	% 21%	-40%	41%-60%	61%	6—80%	81%-100%		7
1D) Calculate the <u>Clinica</u> l <u>Benefit</u> <u>Score</u>		E THAN	ONE. Writ									OR an RR score, llowable points are	Clinical Score 22
Step 2: Determin	e the regime	en's TC	XICITY										
Calculate the Toxicity Score	toxicities of below). The	Grade score	3-5 reporte will be base	ed for each ed on the d	n regimen difference	) and as in toxici	sign a ty bet		ore ( egim	-20 throi iens. Wr	ugh +20 as ite this num	shown	Toxicity Score
246 vs. 184 =	the second s	box labeled "Toxicity Score." The maxim Toxicity Score -20 -			-10	An ar			+10			+20	0
34% increase	Does the new						-		_		1.1.500		
	regimen represent an improvement in toxicity over the standard of toxic		tolerated (75%-100% (5 increase in the in number of Grade 3-5 gr toxicities reported for re		(50%-74% in the numb grade 3-5 t	Less well tolerated (50%-74% increase n the number of grade 3-5 toxicities reported for the new		Toxicity is the same (less than 49% increase and up to 49% fewer toxicities are reported for the new regimen)		74% decrease in the number of Grade 3–5 s toxicities reported for		Substantially better tolerated (75%–100% decrease in the number of Grade 3–5 toxicities reported for the new regimen)	
Step 3: Determin			une new reg	men)	regimen)		nev	vregimen)				the new regimen)	
3A) PALLIATION			ES. If a sta	tisticallv s	ianificant i	improve	ment i	in cancer-re	lated	sympto	ms is report	ed, award 10	Palliation
data related to the symptoms reported	e palliation of	f p	oints and p	lace this in	the box labeled "Palliation Bonus Points." Proceed to Step 3B. are awarded. Proceed to Step 3B.								Points 0
3B) TREATMENT	EDEE			2					free	interval	is reported	award points	Treatment-
INTERVAL BONU related to treatme	JS. Are data	b	ased on the	e table bel	ow, and p	lace this	s in the		d "Cli	nical Be	nefit Bonus	Points." This is the	free Interva Bonus Poin
reported? Treat should be c	ontinued unt	il B	onus Point	s	0	5		10			15	20	0
disease progressi unacceptable toxi	ion or	%	Change I <b>O.</b> No boni		%–19% are award	20%-		36%-499	%	50%	674%	≥75%	U
3C) Calculate Total Bonus Points	Add the Pal	lliation E he box	Bonus Poin labeled "To	ts (Step 3	A) and the	e Treatr	nent-F	Free Interval points availa					Total Bonus Points
Step 4: Determin	e the regime	en's NE	ET HEALTH	BENEFI	т								
Calculate the <u>Net Health</u> <u>Benefit</u>	Add the Clir Benefit Sco Benefit are Proceed to	ore. Writ 130 (10	te this numl )0 + 30 bon	per in the	box labele	core (S ed "Net I	tep 2), Health	and Bonus Benefit." Th	Poin ne ma	ts (Step aximum	3). This yie points avail:	lds a Net Health able for Net Health	Net Health Benefit 22/130
Step 5: Determin													
Insert the drug ac costs per month.	9			nt copay b	ased on h	iow muc	the	treatment re	egime		st per Mont ient Copay	th: <u>\$8670 WAC</u>	
Step 6: Summary	/ Assessme	nt – Ad	vanced Di	sease Fra	mework						Sopay	·	
Clinical Ber			cicity	Bonus I		Net F	lealth	Benefit	Co	st (per m	onth)		
						noti			-	C: \$86			
22/80		0/	20	0/3	0		22/1:	30		tient Pay			

ASCO Value Framework for Advanced Disease: Empliciti: relapsed multiple myeloma patients who have received at least one to three prior treatments. 10 mg/kg for the first two 4 week cycles then every two weeks thereafter

1A) Is <u>Overall</u> Survival (OS)	YES. Assign ar Score." Procee		through 5	as shown be	elow) and	d multip	bly by 16	. Writ	te this n	umber in th	e box labeled "OS	OS Score
reported?	OS Score			1	2	3		4		5		_
	Improvement ir change in medi	an OS)	%	>0%-24% 25%-		49% 50%-75%		76%	new regime		e median OS of the 1, there is a 50% t in the fraction of riving	
	NO. Proceed to 1B. YES. Assign a PFS Score (1 through 5 as shown below) and multiply by 11. Write this number in the box labeled "PFS											
1B) If OS is not reported, is <u>Progression-</u>	Score." Procee		through 5				ply by 11		te this n		e box labeled "PFS	PFS Score
Free Survival	PFS Score			1	2	3	3 4			5		
(PFS) reported? ERD vs. RD 19.4 vs.14.9 = 30% increase	Improvement ir change in medi NO. Proceed	>0%-24%	25%-49	9% 509	%–75%	76%	-100%	new regimer improvemen	e median PFS of the n, there is a 50% t in the fraction of out progression or	22		
1C) If neither	YES. Assign ar	the cardina and a second s	through E	aa ahawa h		d noultin	n lu hu Q		- hould b		d by adding the	RR
OS nor PFS is	complete respo											Score
reported, is Response Rate	RR Score			1	2	3		4		5		
(RR) reported?	What was the r (CR + PR)?	eported respo	nse rate	>0%–20%	21%-40	0% 419	%–60%	61%	-80%	81%-100%		1
1D) Calculate the Clinical Benefit Score		IAN ONE. Writ									OR an RR score, llowable points are	Clinical Score 22
Step 2: Determin	ne the regimen's	TOXICITY										
Calculate the Toxicity Score	For the regimer toxicities of Gra below). The sco box labeled "To	de 3-5 reporte pre will be base	ed for each ed on the	n regimen) a difference in	nd assig toxicity b	n a <u>To</u> betweer	xicity Sco n the 2 r	ore (- egim	-20 throu ens. Wr	ugh +20 as ite this num	shown	Toxicity Score
192 vs 129	Toxicity Score	-20		-10		0	5 410 20.		+10	otop o.	+20	-10
=49% increase	Does the new regimen represent an improvement in toxicity over the standard of care/comparator?	Substantially less well tolerated (75%-100% ( increase in the number of Grade 3-5 toxicities reported for		Less well toler (50%-74% inc in the number grade 3-5 toxi reported for th regimen)	rease (less th of increas cities 49% fe enew are rep		s than 49% ease and up to 6 fewer toxicities		Better tolerated (50%- 74% decrease in the number of Grade 3-5 toxicities reported for the new regimen)		Substantially better tolerated (75%–100% decrease in the number of Grade 3–5 toxicities reported for the new regimen)	
Step 3: Determin	i		interi)	regimeny		newregi	interij				ule new regimen)	
3A) PALLIATION data related to the	BONUS. Are epalliation of	1									ed, award 10 9 <b>3B.</b>	Palliation Points
symptoms reporte	ed?	NO. No bonus points are awarded. Proceed to Step 3B.										0
3B) TREATMENT INTERVAL BONU related to treatme	JS. Are data	based on the	ES. If a statistically significant improvement in treatment-free interval is reported, award points ased on the table below, and place this in the box labeled "Clinical Benefit Bonus Points." This is the terval from completion of study treatment to initiation of next treatment. <b>Proceed to 3C</b> .								Treatment- free Interval Bonus Poin	
reported?		Bonus Point	s	0	5		10			15	20	
Continue treatme progression or un toxicity.		% Change NO. No boni	% Change >0%-19% 20%-35% 36%-49% 50%-74% ≥75%   NO. No bonus points are awarded. Proceed to Step 3C						≥75%	0		
3C) Calculate	alculate Add the Palliation Bonus Points (Step 3.A) and the Treatment-Free Interval Bonus Points (Step 3B). Write this number in the box labeled "Total Bonus Points." The maximum points available for Bonus Points are 30.											Total Bonu Points <b>0</b>
<u>Total Bonus</u> <u>Points</u>	Proceed to Ste	ep 4.										
<u>Total Bonus</u>	Proceed to Ste		H BENEFI	т								
<u>Total Bonus</u> <u>Points</u>	Proceed to Ste ne the regimen's Add the Clinica	NET HEALTH Benefit Score	e (Step 1), ber in the	Toxicity Sco box labeled '							lds a Net Health able for Net Health	Net Health Benefit <b>12</b>
Total Bonus Points Step 4: Determin Calculate the Net Health	Proceed to Ste the regimen's Add the Clinica Benefit Score, V Benefit are 130	NET HEALTH Benefit Score Write this numl (100 + 30 bon	e (Step 1), ber in the	Toxicity Sco box labeled '								Benefit
Total Bonus Points Step 4: Determin Calculate the Net Health Benefit	Proceed to Ste the regimen's Add the Clinica Benefit Score. Benefit are 130 the regimen's	NET HEALTH Benefit Score Write this num (100 + 30 bon	e (Step 1), ber in the lus points)	Toxicity Sco box labeled ' I.	"Net Hea	alth Ber	nefit." Th	e ma	n <b>Co</b>	points avails st per Mont	able for Net Health th: \$9472 (80 kg)	Benefit
Total Bonus Points Step 4: Determin Calculate the Net Health Benefit Step 5: Determin Insert the drug ac	Proceed to Ste the regimen's Add the Clinica Benefit Score. N Benefit are 130 the the regimen's equisition cost (D	NET HEALTH Benefit Score Write this num (100 + 30 bon COST AC) and patier	e (Step 1), ber in the sus points) nt copay b	Toxicity Sco box labeled ' i. ased on how	"Net Hea	alth Ber	nefit." Th	e ma	n <b>Co</b>	points avail	able for Net Health th: \$9472 (80 kg)	Benefit
Total Bonus Points Step 4: Determin Calculate the Net Health Benefit Step 5: Determin Insert the drug ac costs per month.	Proceed to Ste the regimen's Add the Clinica Benefit Score. 1 Benefit are 130 the the regimen's equisition cost (D. y Assessment –	NET HEALTH Benefit Score Write this num (100 + 30 bon COST AC) and patier	e (Step 1), ber in the sus points) nt copay b	Toxicity Sco box labeled ' ased on how	"Net Hea	alth Ber	nefit." Th	e ma gime	n <b>Co</b>	points avail st per Mont ient Copay	able for Net Health th: \$9472 (80 kg)	Benefit

ASCO Value Framework for Advanced Disease: Farydak: relapsed multiple myeloma patients who have received at least two prior treatments; 3 doses per week in Weeks 1 and 2 of each 21-day cycle for up to 8 cycles

Suprival (OO)			through 5	as shown be	elow) an	d multip	ly by 16.	Writ	e this nu	umber in the	e box labeled "OS	os	
Survival (OS) reported?	Score." Procee	u to TD.		1	2	3		4		5		Score	
	Improvement ir change in medi		%	>0%-24%	25%-4	- U	%—75%		-100%	At double the new regimen	e median OS of the I, there is a 50% t in the fraction of iving		
	NO. Proceed t												
<b>1B)</b> If OS is not reported, is Progression-	Score." Procee		through 5	as shown be			bly by 11	. Writ	te this n		e box labeled "PFS	PFS Score	
Free Survival	PFS Score			1	2	3		4		5			
(PFS) reported? FVD vs. VD 10.6 vs. 5.8 = 82% increase	Improvement ir change in medi	>0%-24%	25%-4	9% 50%	%–75%	76%–100%		At double the median PFS of the new regimen, there is a 50% improvement in the fraction of patients without progression or death		44			
1C) If neither	5.6.5.2 31.35.53.53.54.54.54.54.54.54		through E	aa ahawa h		d multin			bould b		hy adding the	DD	
OS nor PFS is reported, is	complete respo			ponse (PR)	rates. W	/rite this		r in the box la		be calculated by adding the abeled "RR Score."		RR Score	
Response Rate	RR Score			1	2	3		4		5		_	
(RR) reported?	What was the r (CR + PR)?	eported respo	nse rate	>0%–20%	21%-4	0% 419	%–60%	61%	-80%	81%-100%			
1D) Calculate the Clinical Benefit Score		AN ONE. Writ									OR an RR score, lowable points are	Clinical Score <b>44</b>	
Step 2: Determin	ne the regimen's	TOXICITY											
Calculate the Toxicity Score 281 vs. 106 =	For the regiment toxicities of Gra below). The source box labeled "To	ade 3-5 reporte ore will be base	ed for each ed on the o	n regimen) a difference in	nd assig toxicity l	gn a <u>Tox</u> betweer	<u>kicity Sco</u> n the 2 re	ore (- egim	20 throu ens. Wri	igh +20 as te this num	shown	Toxicity Score	
165% increase	Toxicity Score	-20		-10		0			+10		+20	-20	
	Does the new regimen represent an improvement in toxicity over the standard of care/comparator?	tolerated (7 increase in number of C toxicities rep	tolerated (75%-100%) ( increase in the in number of Grade 3-5 g toxicities reported for in		ated rease of cities e new	ease (less than 49% of increase and u ities 49% fewer toxi		to number of toxicities		blerated (50%- Substantially better tolerated (75%-100' of Grade 3- s reported for r regimen) toxicities reported fo the new regimen)			
Step 3: Determin			imen)	regimen)		new regir	men)				the new regimen)		
3A) PALLIATION	BONUS. Are	YES. If a sta									ed, award 10	Palliation	
data related to the symptoms reported				the box labeled "Palliation Bonus Points." Proceed to Step 3B. re awarded. Proceed to Step 3B.								Bonus Points	
3B) TREATMENT INTERVAL BONU related to treatme	US. Are data	based on the	e table bel	ignificant improvement in treatment-free interval is reported, award points ow, and place this in the box labeled "Clinical Benefit Bonus Points." This is th on of study treatment to initiation of next treatment. <b>Proceed to 3C</b> .						Points." This is the	Treatment- free Interva Bonus Poir		
reported?	······	Bonus Point		0	5		10			15	20		
8 21-day cycles w	vith an additional he patient has	% Change	>0%	6–19%	20%-35%	6	36%-49%	6	50%	-74%	≥75%	10	
0 07005 011055 []		NO. No bon	us points a		Procee	d to St	ep 3C						
severe or signific	1												
severe or signific 3C) Calculate <u>Total Bonus</u> <u>Points</u>	Add the Palliati number in the b Proceed to Ste	oox labeled "To ap 4.	otal Bonus	A) and the T Points." The	reatme	nt-Free						Total Bonu Points <b>0</b>	
severe or signific 3C) Calculate Total Bonus	number in the b Proceed to Standard	oox labeled "To op 4. NET HEALTH	H BENEFI	A) and the T Points." The T	reatme maxim	nt-Free um poin	its availa	able f	or Bonu	s Points are	9 30.	Points 0	
severe or signific 3C) Calculate <u>Total Bonus</u> <u>Points</u>	number in the b Proceed to Standard of the regimen's Add the Clinica	oox labeled "To op 4. NET HEALTH I Benefit Score Write this num	HBENEFI (Step 1), ber in the	.A) and the T Points." The <b>T</b> Toxicity Sco pox labeled <sup>6</sup>	reatmer maxim	nt-Free um poin 2), and	its availa	able f	or Bonu	s Points are		Points	
severe or signific: 3C) Calculate <u>Total Bonus</u> <u>Points</u> Step 4: Determir Calculate the <u>Net Health</u>	number in the b Proceed to Ste ne the regimen's Add the Clinica Benefit Score. <sup>1</sup> Benefit are 130	oox labeled "To op 4. NET HEALTH I Benefit Score Write this numi (100 + 30 bon	HBENEFI (Step 1), ber in the	.A) and the T Points." The <b>T</b> Toxicity Sco pox labeled <sup>6</sup>	reatmer maxim	nt-Free um poin 2), and	its availa	able f	or Bonu	s Points are	e 30. Ids a Net Health	Points 0 Net Health Benefit	
severe or signific 3C) Calculate <u>Total Bonus</u> <u>Points</u> <b>Step 4: Determir</b> Calculate the <u>Net Health</u> <u>Benefit</u>	number in the b Proceed to Sta ne the regimen's Add the Clinica Benefit Score. 1 Benefit are 130 ne the regimen's	NET HEAL TH NET HEAL TH Benefit Score Write this numi (100 + 30 bon COST	H BENEFI (Step 1), ber in the us points)	A) and the T Points." The Toxicity Sco box labeled f	reatme e maxim ere (Step "Net Hea	nt-Free um poin 2), and alth Ben	its availa I Bonus I hefit." The	Point e ma	s (Step ximum p	s Points are 3). This yiel points availa	e 30. Ids a Net Health able for Net Health ih: \$11,000 WAC	Points 0 Net Health Benefit	
severe or signific: 3C) Calculate <u>Total Bonus</u> <u>Points</u> Step 4: Determin Calculate the Net <u>Health</u> <u>Benefit</u> Step 5: Determin Insert the drug ac	number in the b Proceed to Sta ne the regimen's Add the Clinica Benefit Score. Benefit are 130 ne the regimen's cquisition cost (D	NET HEALTH NET HEALTH Benefit Score Write this numi (100 + 30 bon COST AC) and patier	H BENEFI (Step 1), ber in the us points)	A) and the T Points." The Toxicity Sco box labeled ' ased on how	reatme e maxim ere (Step "Net Hea	nt-Free um poin 2), and alth Ben	its availa I Bonus I hefit." The	Point e ma	s (Step ximum p	3). This yiel a). This yiel boints availa	e 30. Ids a Net Health able for Net Health ih: \$11,000 WAC	Points 0 Net Health Benefit	
severe or signific: 3C) Calculate <u>Total Bonus</u> <u>Points</u> Step 4: Determir Calculate the <u>Net Health</u> <u>Benefit</u> Step 5: Determir Insert the drug ac costs per month.	Add the Clinica Benefit Score. J Benefit Score. J Benefit are 130 ne the regimen's cquisition cost (D	NET HEALTH NET HEALTH Benefit Score Write this numi (100 + 30 bon COST AC) and patier	H BENEFI (Step 1), ber in the us points)	A) and the T Points." The T Toxicity Sco box labeled f ased on how	reatme e maxim ere (Step "Net Hea	nt-Free um poin 2), and alth Ben he treat	I Bonus I hefit." The	point e ma	s (Step ximum p	3). This yiel 3). This yiel points availa t per Mont lent Copay	e 30. Ids a Net Health able for Net Health ih: \$11,000 WAC	Points 0 Net Health Benefit	

ASCO Value Framework for Advanced Disease: Kyprolis: indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies; 6 doses per 28 day cycle 27 mg/m(2)

Step 1: Determin	e the regimen'	s CLINICAL B	ENEFIT					,				
1A) Is <u>Overall</u> <u>Survival</u> (OS)	YES. Assign a Score." Proce		through 5	as shown l	below) ai	nd m	ultiply by 16	5. Writ	te this n	umber in th	e box labeled "OS	OS Score
reported?	OS Score			1	2		3	4		5		
<b>24 mo OS</b> 73.3% vs. 65%	Improvement in median OS (% change in median OS)			>0%-24%	6 25%-	49%	50%-75%	76%	100%	% At double the median OS of the new regimen, there is a 50% improvement in the fraction of patients surviving		
	NO. Proceed	12	6		8							
<b>1B)</b> If OS is not reported, is Progression-	Score." Proce		through 5	as shown	below) a	nd m			te this n		e box labeled "PFS	PFS Score
Free Survival	PFS Score			1	2		3	4		5		22
(PFS) reported? KRD vs. RD 26.3 vs. 17.6 = 49.4%	Improvement in median PFS (% change in median PFS)			>0%-24%	6 25%-	49%	50%-75%	76%		new regimer	e median PFS of the n, there is a 50% ti in the fraction of progression or death	
	NO. Proceed to 1C YES. Assign an RR Score (1 through 5 as shown below) and multiply by 8. RR should be calculated by adding the											
1C) If neither OS nor PFS is reported, is	complete resp	n <u>RR Score</u> (1 onse (CR) and			R) rates. N		this numbe	r in the box la		abeled "RR		RR Score
Response Rate	RR Score			1	2		3	4		5		
(RR) reported?	(CR + PR)?	reported respo		>0%-20%	··· ··································	104.155	41%–60%		-80%	81%-100%	standar standar	
1D) Calculate the <u>Clinical Benefit</u> <u>Score</u>		HAN ONE. Wri									OR an RR score, llowable points are	Clinical Score <b>22</b>
Step 2: Determin	_											
Calculate the Toxicity Score	toxicities of Gr below). The sc	ens being asses ade 3–5 report core will be bas oxicity Score."	ed for eac ed on the	h regimen) difference i	) and ass in toxicity	ign a / betv	Toxicity Sc ween the 2 r	ore (-	20 thro ens. Wr	ugh +20 as ite this num	shown	Toxicity Score
170 vs. 110 = 55% increase	T 111 0 00			-10 0				+10			+20	-10
	Does the new	Substantial			Less well tolerated		Toxicity is the same		Pottor tol	erated (50%-	Substantially better	
	tolerated (75%-100%) an improvementin toxicity over the standard of care/comparator?		5%–100% the Grade 3–5 ported for	00% (50%-74% in in the number 3-5 grade 3-5 tox for reported for th		increase (less than 49 er of increase and oxicities 49% fewer to		to number ties toxicitie		rease in the of Grade 3–5 reported for regimen)	tolerated (75%-100% decrease in the number of Grade 3-5 toxicities reported for the new regimen)	
Step 3: Determin	e BONUS POIN	ITS										
3A) PALLIATION		YES. If a sta	tistically s	ignificant ir	mprovem	nent i	n cancer-re	lated	sympto	ms is repor	ted, award 10	Palliation Bonus
data related to the symptoms reported			points and place this in the box labeled "Palliation Bonus Points." Proceed to Step 3B. NO. No bonus points are awarded. Proceed to Step 3B.									
3B) TREATMENT INTERVAL BONU	JS. Are data	based on the	YES. If a statistically significant improvement in treatment-free interval is reported, award points based on the table below, and place this in the box labeled "Clinical Benefit Bonus Points." This is the							Points." This is the	Treatment- free Interval	
related to treatme reported?	<u>nt-free interva</u> l	free interval interval from completion		on of study		nt to	1		reatme			Bonus Point
Treatment may be	continued until	Bonus Point	s	0	5		10			15	20	0
disease progressio unacceptable toxic		% Change		%–19%	20%-35		36%-499	%	50%	6-74%	≥75%	U
3C) Calculate Total Bonus Points	Add the Palliat	NO. No bon ion Bonus Poir box labeled "To ep 4.	ts (Step 3	.A) and the	e Treatme	ent-F	ree Interval					Total Bonus Points <b>0</b>
Step 4: Determin	e the regimen'	s NET HEALT	H BENEFI	т								
Calculate the <u>Net Health</u> <u>Benefit</u>	Add the Clinica	al Benefit Score Write this num	e (Step 1), ber in the	Toxicity Se box labele							lds a Net Health able for Net Health	Net Health Benefit <b>12</b>
Step 5: Determin	e the regimen'	s COST										
Insert the drug ac costs per month.	quisition cost (E	AC) and patier	nt copay b	ased on he	ow much	the t	treatment re	egime			th: \$11,171 ':	
Step 6: Summary	Assessment -	- Advanced Di	sease Fra	amework					1.0.0	,,		
Clinical Ber		Toxicity	Bonus		Net He	alth	Benefit	Cos	st (per m	nonth)		
22/80		-10/20	0/3	0	2	12/13	30	WA	.C: \$11 ient Pay	,171		
								1	. Since dy			

## ASCO Value Framework for Advanced Disease: Daratumumab

	Score." Procee		rough 5 a	as shown be	elow) and	d multiply by 1	6. Write	this number in	the box labeled "OS	OS Score
reported?	OS Score			1	2	3	4	5		]
	Improvement in change in media	median OS (% an OS)		>0%-24%	25%-49	9% 50%-75%	76%–1	new regi	the median OS of the nen, there is a 50% nent in the fraction of urviving	
	NO. Proceed to	o 1B.								
<b>1B)</b> If OS is not reported, is <u>Progression-</u>	Score." Procee		rough 5 a	1	-		T		the box labeled "PFS	PFS Score
Free Survival	PFS Score			1	2	3	4	5		_
(PFS) reported?	Improvement in median PFS (% change in median PFS)			>0%-24% 25%-		9% 50%-75%	76%–1	new regil	new regimen, there is a 50% improvement in the fraction of patients without progression or	
	NO. Proceed t	o 1C		12		25. 				
1C) If neither OS nor PFS is reported, is	YES. Assign an complete respo Proceed to 1D.	nse (CR) and pa							ted by adding the R Score."	RR Score
Response Rate	RR Score			1	2	3	4	5		-
(RR) reported?	What was the re (CR + PR)?	eported respons	e rate	>0%-20%	21%-40	0% 41%-60%	61%-6	30% 81%-100	%	
1D) Calculate the <u>Clinical Benefit</u> <u>Score</u>		AN ONE. Write							re OR an RR score, a allowable points are	Clinical Benefit Score
Step 2: Determin	ne the regimen's	TOXICITY								
Calculate the Toxicity Score	For the regiment toxicities of Gra	ns being assesse de 3–5 reported pre will be based	for each on the d	i regimen) a lifference in	nd assig toxicity b	n a <u>Toxicity S</u> between the 2	core (-2) regimer	0 through +20 ns. Write this n	as shown	Toxicity Score
	Toxicity Score	-20		-10		0		10	+20	
	Does the new regimen represent	ew Substantially less well present tolerated (75%–100% increase in the or the number of Grade 3–5 f toxicities reported for		Less well toler (50%–74% inc	ated	Toxicity is the sau (less than 49%	me Be	etter tolerated (50%	- Substantially better	
	an improvement in toxicity over the standard of	number of Gra	ade 3-5	in the number grade 3–5 toxi	of	increase and up 49% fewer toxicit	to nu ies to	4% decrease in the umber of Grade 3- xicities reported for e new regimen)	5 decrease in the r number of Grade 3–5	
	toxicity over the standard of care/comparator?	number of Gra toxicities repo the new regim	ade 3–5 rted for	in the number	of cities e new	increase and up	to nu ies to	umber of Grade 3-	5 decrease in the	
Step 3: Determin	toxicity over the standard of care/comparator?	number of Gra toxicities repo the new regim	ade 3–5 rted for en)	in the number grade 3–5 toxi reported for th regimen)	of cities e new	increase and up 49% fewer toxicit are reported for t new regimen)	to nu ies to he th	umber of Grade 3- xicities reported fo e new regimen)	5 decrease in the r number of Grade 3–5 toxicities reported for the new regimen)	Dellistics
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