

Supplementary Material

The Urgency Numeric Rating Scale: Psychometric Evaluation in Adults with Crohn's Disease

Marla Dubinsky,¹ Aisha Vadhariya,^{2*} Sylvia Su,² Xian Zhou,³ Frederick Durand,² Claudine Clucas,⁴ Larissa Stassek,⁵ Ariane K. Kawata,⁵ Simon Travis⁶

¹Dr. Henry D. Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA

²Eli Lilly and Company, Indianapolis, IN, USA

³Syneos Health, Morrisville, NC, USA

⁴Evidera, London, UK

⁵Evidera, Wilmington, NC, USA

⁶Kennedy Institute, Translational Gastroenterology Unit and Biomedical Research Centre, University of Oxford, Oxford, UK

***Corresponding author:** Aisha Vadhariya (vadhariya_aisha@lilly.com)

893 S Delaware St. Indianapolis, IN 46225, USA

Table S1 Summary of assessment values at Baseline, Week 12, and Week 52

Assessment	N	Baseline		N	Week 12		N	Week 52	
		Mean (SD)	Median (range)		Mean (SD)	Median (range)		Mean (SD)	Median (range)
PGRS average score	1063	4.5 (0.8)	4.4 (1.0, 6.0)	1016	3.2 (1.2)	3.1 (1.0, 6.0)	859	2.5 (1.2)	2.3 (1.0, 6.0)
PGIC	–	–	–	1014	2.7 (1.2)	3.0 (1.0, 7.0)	855	2.0 (1.0)	2.0 (1.0, 7.0)
IBDQ total score	1061	127.3 (33.4)	128.0 (37.0, 213.0)	1014	163.1 (34.4)	168.0 (55.0, 223.0)	856	178.1 (29.6)	184.0 (53.0, 224.0)
IBDQ Bowel Symptom domain score	1061	37.8 (9.7)	38.0 (11.0, 66.0)	1014	51.1 (11.0)	52.0 (16.0, 70.0)	856	56.1 (9.3)	58.0 (18.0, 70.0)
IBDQ item 1 (bowel movement frequency)	1061	3.4 (1.6)	3.0 (1.0, 7.0)	1014	5.5 (1.7)	6.0 (1.0, 7.0)	856	5.9 (1.5)	7.0 (1.0, 7.0)
CDAI score	1052	321.1 (87.9)	316.9 (71.5, 726.3)	998	195.7 (106.9)	180.5 (0.0, 655.6)	845	130.2 (90.5)	118.0 (0.0, 538.3)
SES-CD	1065	13.5 (6.5)	11.7 (4.0, 35.5)	929	9.1 (6.5)	8.0 (0.0, 36.0)	865	6.5 (5.5)	5.7 (0.0, 31.5)
hsCRP (mg/L)	1065	18.4 (26.7)	8.3 (0.0, 314.0)	992	10.2 (17.4)	4.7 (0.0, 245.0)	849	7.6 (14.1)	3.1 (0.0, 173.0)
Fecal calprotectin (mg/kg)	835	2333.6 (3726.4)	1315.0 (15.0, 31680.0)	281	1031.7 (2536.1)	384.0 (15.0, 31680.0)	287	721.3 (1201.2)	210.0 (15.0, 8689.0)

CDAI Crohn's Disease Activity Index, *hsCRP* high-sensitivity C-reactive protein, *IBDQ* Inflammatory Bowel Disease Questionnaire, *PGIC* Patient

Global Impression of Change, *PGRS* Patient Global Rating of Severity, *SD* standard deviation, *SES-CD* Simple Endoscopic Score for Crohn's Disease

Table S2 Convergent and discriminant validity of the Urgency NRS

	Baseline		Week 12		Week 52	
	N	r (95% CI)	N	r (95% CI)	N	r (95% CI)
PGRS average	1063	0.48 (0.43, 0.53)****	1016	0.66 (0.63, 0.70)****	859	0.65 (0.61, 0.69)****
IBDQ Bowel Symptom domain	1060	-0.37 (-0.42, -0.32)****	1009	-0.56 (-0.60, -0.51)****	836	-0.54 (-0.59, -0.49)****
IBDQ total score	1060	-0.31 (-0.37, -0.26)****	1009	-0.50 (-0.54, -0.45)****	835	-0.49 (-0.54, -0.44)****
CDAI	1052	0.48 (0.43, 0.53)****	998	0.67 (0.64, 0.71)****	845	0.64 (0.60, 0.68)****
SES-CD	1064	0.12 (0.06, 0.18)****	925	0.14 (0.08, 0.20)****	843	0.13 (0.06, 0.20)***
hsCRP (mg/L)	1064	0.07 (0.01, 0.13)*	987	0.14 (0.07, 0.20)****	828	0.20 (0.13, 0.26)****
Fecal calprotectin (mg/kg)	835	0.03 (-0.04, 0.09)	278	0.16 (0.04, 0.27)*	281	0.04 (-0.07, 0.16)

*p <0.05; ***p <0.001; ****p <0.0001

CDAI Crohn's Disease Activity Index, *CI* confidence interval, *hsCRP* high-sensitivity C-reactive protein, *IBDQ* Inflammatory Bowel Disease Questionnaire, *NRS* Numeric Rating Scale, *PGRS* Patient Global Rating of Severity, *SES-CD* Simple Endoscopic Score for Crohn's Disease

Table S3 Convergent and discriminant validity of the Urgency NRS by disease location

Disease location		Baseline		Week 12		Week 52	
		N	r (95% CI)	N	r (95% CI)	N	r (95% CI)
Ileal	PGRS average	113	0.55 (0.41, 0.67)****	103	0.65 (0.52, 0.75)****	91	0.60 (0.45, 0.72)****
	IBDQ Bowel Symptom domain	112	-0.29 (-0.45, -0.11)*	102	-0.52 (-0.65, -0.37)****	88	-0.48 (-0.63, -0.30)****
	IBDQ total score	112	-0.32 (-0.47, -0.14)***	102	-0.46 (-0.60, -0.29)****	88	-0.48 (-0.62, -0.30)****
	CDAI	111	0.42 (0.25, 0.56)****	102	0.71 (0.60, 0.80)****	91	0.66 (0.53, 0.76)****
	SES-CD	113	0.11 (-0.08, 0.29)	93	-0.05 (-0.25, 0.16)	91	-0.03 (-0.23, 0.18)
Colonic	PGRS average	421	0.55 (0.48, 0.61)****	405	0.71 (0.66, 0.75)****	340	0.70 (0.64, 0.75)****
	IBDQ Bowel Symptom domain	421	-0.42 (-0.50, -0.34)****	400	-0.63 (-0.68, -0.57)****	328	-0.54 (-0.61, -0.45)****
	IBDQ total score	421	-0.37 (-0.45, -0.28)****	400	-0.57 (-0.63, -0.50)****	327	-0.50 (-0.58, -0.42)****
	CDAI	418	0.52 (0.45, 0.59)****	395	0.71 (0.66, 0.76)****	330	0.67 (0.60, 0.72)****
	SES-CD	422	0.05 (-0.04, 0.15)	368	0.20 (0.09, 0.29)***	329	0.18 (0.08, 0.28)***
Ileal-colonic	PGRS average	529	0.41 (0.34, 0.48)****	508	0.63 (0.57, 0.68)****	428	0.62 (0.56, 0.68)****
	IBDQ Bowel Symptom domain	527	-0.34 (-0.41, -0.26)****	507	-0.49 (-0.56, -0.43)****	420	-0.55 (-0.61, -0.48)****
	IBDQ total score	527	-0.27 (-0.35, -0.19)****	507	-0.44 (-0.51, -0.37)****	420	-0.48 (-0.55, -0.40)****
	CDAI	523	0.46 (0.39, 0.52)****	501	0.63 (0.58, 0.68)****	424	0.63 (0.56, 0.68)****
	SES-CD	529	0.13 (0.05, 0.22)*	464	0.12 (0.03, 0.21)*	423	0.12 (0.03, 0.21)*

*p <0.05; ***p <0.001; ****p <0.0001

CDAI Crohn's Disease Activity Index, CI confidence interval, IBDQ Inflammatory Bowel Disease Questionnaire, NRS Numeric Rating Scale, PGRS

Patient Global Rating of Severity, SES-CD Simple Endoscopic Score for Crohn's Disease

Table S4 Known-groups validity of the Urgency NRS by PGRS at Baseline

PGRS score	1=None	2=Very mild	3=Mild	4=Moderate	5=Severe	6=Very severe
Urgency NRS scores	N=3	N=14	N=85	N=457	N=415	N=89
Mean (SD)	4.3 (4.04)	5.0 (2.4)	5.0 (1.9)	6.0 (1.9)	7.2 (1.9)	8.5 (1.9)
Median (range)	5.0 (0.0, 8.0)	5.4 (1.0, 8.0)	4.9 (0.0, 10.0)	6.1 (0.0, 10.0)	7.6 (0.0, 10.0)	9.0 (1.0, 10.0)
LSM (SE)	4.3 (1.1)	5.0 (0.5)	5.0 (0.2)	6.0 (0.1)	7.2 (0.1)	8.5 (0.2)
LSMD (CI)						
vs. 1=None		0.7 (−3.4, 4.8)	0.7 (−3.1, 4.4)	1.7 (−2.0, 5.4)	2.8 (−0.9, 6.5)	4.2 (0.4, 7.9)*
vs. 2=Very mild			−0.0 (−1.9, 1.8)	1.0 (−0.7, 2.7)	2.1 (0.4, 3.9)**	3.5 (1.6, 5.3)****
vs. 3=Mild				1.0 (0.3, 1.8)**	2.2 (1.4, 2.9)****	3.5 (2.5, 4.4)****
vs. 4=Moderate					1.1 (0.7, 1.6)****	2.5 (1.7, 3.2)****
vs. 5=Severe						1.3 (0.6, 2.1)****

*p <0.05, **p <0.01, ****p <0.0001. The pairwise LSMD (CI) and p-values were adjusted using Scheffé's correction

CI confidence interval, LSM least square mean, LSMD least square mean difference, NRS Numeric Rating Scale, PGRS Patient Global Rating of Severity, SD standard deviation, SE standard error

Table S5 Known-groups validity of the Urgency NRS by PGRS at Week 12

PGRS score	1=None	2=Very mild	3=Mild	4=Moderate	5=Severe	6=Very severe
Urgency NRS scores	N=107	N=211	N=274	N=289	N=109	N=26
Mean (SD)	1.1 (1.5)	2.8 (2.2)	3.8 (2.1)	5.4 (2.1)	6.9 (2.1)	9.1 (1.1)
Median (range)	0.4 (0.0, 8.0)	2.0 (0.0, 8.9)	3.5 (0.0, 9.7)	5.6 (0.0, 10.0)	7.2 (0.3, 10.0)	9.5 (6.3, 10.0)
LSM (SE)	1.1 (0.2)	2.8 (0.1)	3.8 (0.1)	5.4 (0.1)	6.9 (0.2)	9.1 (0.4)
LSMD (CI)						
vs. 1=None		1.7 (0.9, 2.5)****	2.7 (1.9, 3.5)****	4.3 (3.6, 5.1)****	5.8 (4.9, 6.7)****	8.0 (6.5, 9.5)****
vs. 2=Very mild			1.0 (0.3, 1.6)****	2.6 (2.0, 3.2)****	4.1 (3.2, 4.9)****	6.3 (4.9, 7.7)****
vs. 3=Mild				1.6 (1.0, 2.2)****	3.1 (2.3, 3.9)****	5.3 (3.9, 6.7)****
vs. 4=Moderate					1.5 (0.7, 2.2)****	3.7 (2.3, 5.1)****
vs. 5=Severe						2.2 (0.7, 3.7)***

p <0.001, *p <0.0001. The pairwise LSMD (CI) and p-values were adjusted using Scheffé's correction

CI confidence interval, LSM least square mean, LSMD least square mean difference, NRS Numeric Rating Scale, PGIC Patient Global Impression of Change, PGRS Patient Global Rating of Severity, SD standard deviation, SE standard error

Table S6 Known-groups validity of the Urgency NRS by PGRS at Week 52

PGRS score	1=None	2=Very mild	3=Mild	4=Moderate	5=Severe	6=Very severe
Urgency NRS scores	N=226	N=234	N=222	N=134	N=41	N=2
Mean (SD)	1.2 (1.7)	2.1 (1.7)	3.5 (2.1)	4.8 (2.3)	7.1 (2.2)	8.8 (1.7)
Median (range)	0.4 (0.0, 10.0)	2.0 (0.0, 9.4)	3.1 (0.0, 10.0)	4.9 (0.0, 10.0)	7.4 (1.0, 10.0)	8.8 (7.6, 10.0)
LSM (SE)	1.2 (0.1)	2.1 (0.1)	3.5 (0.1)	4.8 (0.2)	7.1 (0.3)	8.8 (1.4)
LSMD (CI)						
vs. 1=None		0.9 (0.3, 1.5)****	2.3 (1.7, 2.9)****	3.6 (2.9, 4.3)****	5.9 (4.8, 7.0)****	7.6 (3.0, 12.2)****
vs. 2=Very mild			1.4 (0.8, 2.0)****	2.7 (2.0, 3.4)****	5.0 (3.9, 6.0)****	6.7 (2.1, 11.2)***
vs. 3=Mild				1.3 (0.6, 2.0)****	3.5 (2.4, 4.6)****	5.3 (0.7, 9.8)*
vs. 4=Moderate					2.3 (1.1, 3.4)****	4.0 (-0.6, 8.6)
vs. 5=Severe						1.7 (-2.9, 6.4)

*p <0.05, ***p <0.001, ****p <0.0001. The pairwise LSMD (CI) and p-values were adjusted using Scheffé's correction

CI confidence interval, LSM least square mean, LSMD least square mean difference, NRS Numeric Rating Scale, PGRS Patient Global Rating of Severity, SD standard deviation, SE standard error

Table S7 Known-groups validity of the Urgency NRS by IBDQ Bowel Symptom domain at Baseline, Week 12, and Week 52

	IBDQ Bowel Symptom domain score $\leq$ median	IBDQ Bowel Symptom domain score $>$ median
Urgency NRS score at Baseline	N=543	N=517
Mean (SD)	7.2 (1.9)	5.9 (2.1)
Median (range)	7.6 (0.3, 10.0)	6.1 (0.0, 10.0)
LS Mean (SE)	7.2 (0.1)	5.9 (0.1)
LSMD (95%CI)		-1.3 (-1.5, -1.0)****
Urgency NRS score at Week 12	N=509	N=500
Mean (SD)	5.4 (2.6)	3.0 (2.3)
Median (range)	5.7 (0.0, 10.0)	2.6 (0.0, 10.0)
LS Mean (SE)	5.4 (0.11)	3.0 (0.1)
LSMD (95%CI)		-2.5 (-2.8, -2.1)****
Urgency NRS score at Week 52	N=438	N=398
Mean (SD)	3.9 (2.5)	1.7 (1.9)
Median (range)	3.6 (0.0, 10.0)	1.1 (0.0, 10.0)
LS Mean (SE)	3.9 (0.1)	1.7 (0.1)
LSMD (95%CI)		-2.2 (-2.5, -1.9)****

****All comparisons between both IBDQ Bowel Symptom domain score groups reached a significance

level of $p < 0.0001$

CI confidence interval, *IBDQ* Inflammatory Bowel Disease Questionnaire, *LSM* least square mean, *LSMD*

least square mean difference, *NRS* Numeric Rating Scale, *SD* standard deviation, *SE* standard error

Table S8 Known-groups validity of the Urgency NRS by IBDQ total score at Baseline, Week 12, and Week 52

	IBDQ total score ≤ median	IBDQ total score > median
Urgency NRS score at Baseline	N=530	N=530
Mean (SD)	7.1 (2.0)	6.1 (2.1)
Median (range)	7.4 (0.0, 10.0)	6.3 (0.0, 10.0)
LS Mean (SE)	7.1 (0.1)	6.1 (0.1)
LSMD (95%CI)		-0.9 (-1.2, -0.7)
Urgency NRS score at Week 12	N=510	N=499
Mean (SD)	5.3 (2.7)	3.1 (2.3)
Median (range)	5.6 (0.0, 10.0)	2.7 (0.0, 10.0)
LS Mean (SE)	5.3 (0.1)	3.1 (0.1)
LSMD (95%CI)		-2.3 (-2.6, -1.9)
Urgency NRS score at Week 52	N=424	N=411
Mean (SD)	3.9 (2.6)	1.9 (1.9)
Median (range)	3.4 (0.0, 10.0)	1.3 (0.0, 9.1)
LS Mean (SE)	3.9 (0.1)	1.9 (0.1)
LSMD (95%CI)		-2.0 (-2.3, -1.7)

****All comparisons between both IBDQ total score groups reached a significance level of $p < 0.0001$

CI confidence interval, *IBDQ* Inflammatory Bowel Disease Questionnaire, *LSM* least square mean, *LSMD* least square mean difference, *NRS* Numeric Rating Scale, *SD* standard deviation, *SE* standard error

Table S9 Score change correlations of the Urgency NRS with anchor measures

Score change correlations with the Urgency NRS	Baseline to Week 12		Baseline to Week 52	
	N	Spearman <i>r</i> (95% CI)	N	Spearman <i>r</i> (95% CI)
PGRS average change	1014	0.70 (0.67, 0.73)****	858	0.63 (0.59, 0.67)****
PGIC	1008	0.49 (0.44, 0.53)****	834	0.34 (0.28, 0.40)****
IBDQ Bowel Symptom domain change	1004	-0.49 (-0.54, -0.45)****	833	-0.44 (-0.50, -0.39)****
IBDQ item 1 (bowel frequency) change	1004	-0.41 (-0.46, -0.35)****	833	-0.35 (-0.41, -0.29)****
IBDQ total score change	1004	-0.46 (-0.51, -0.41)****	833	-0.41 (-0.46, -0.35)****
CDAI score change	987	0.72 (0.68, 0.74)****	838	0.64 (0.60, 0.68)****

****All comparisons reached a significance level of $p < 0.0001$

CDAI Crohn's Disease Activity Index, *CI* confidence interval, *IBDQ* Inflammatory Bowel Disease

Questionnaire, *NRS* Numeric Rating Scale, *PGIC* Patient Global Impression of Change, *PGRS* Patient
Global Rating of Severity

Table S10 Responsiveness of the Urgency NRS by PGIC at Weeks 12 and 52

PGIC categories	Very much better	Much better	A little better	No change	A little worse	Much worse	Very much worse
Urgency NRS score change from Baseline to Week 12	N=154	N=325	N=308	N=159	N=33	N=21	N=8
LSM (SE)	-4.5 (0.2)	-3.2 (0.1)	-1.8 (0.1)	-0.8 (0.2)	-0.5 (0.4)	-0.3 (0.4)	0.7 (0.7)
LSMD (CI)							
vs. very much better		-1.3 (-2.0, -0.6)****	-2.7 (-3.4, -2.0)****	-3.7 (-4.5, -2.8)****	-4.0 (-5.4, -2.6)****	-4.1 (-5.8, -2.4)****	-5.2 (-7.8, -2.5)****
vs. much better			-1.4 (-1.9, -0.8)****	-2.3 (-3.0, -1.6)****	-2.7 (-4.0, -1.4)****	-2.8 (-4.5, -1.2)****	-3.8 (-6.4, -1.2)***
vs. a little better				-1.0 (-1.7, -0.2)**	-1.3 (-2.6, 0.0)	-1.4 (-3.1, 0.2)	-2.5 (-5.1, 0.2)
vs. no change					-0.4 (-1.8, 1.0)	-0.5 (-2.2, 1.2)	-1.5 (-4.1, 1.1)
vs. a little worse						-0.1 (-2.2, 1.9)	-1.1 (-4.0, 1.7)
vs. much worse							-1.0 (-4.0, 2.0)
Urgency NRS score change from Baseline to Week 52	N=280	N=349	N=146	N=40	N=12	N=3	N=4
LSM (SE)	-4.8 (0.1)	-3.5 (0.1)	-2.4 (0.2)	-2.1 (0.3)	-1.6 (0.6)	2.4 (1.2)	-4.1 (1.1)
LSMD (CI)							
vs. very much better		-1.3 (-1.9, -0.7)****	-2.4 (-3.2, -1.6)****	-2.7 (-4.0, -1.4)****	-3.2 (-5.5, -0.9)***	-7.2 (-11.6, -2.7)****	-0.7 (-4.6, 3.1)
vs. much better			-1.1 (-1.8, -0.3)***	-1.4 (-2.7, -0.1)*	-1.9 (-4.2, 0.3)	-5.9 (-10.3, -1.4)**	0.6 (-3.3, 4.4)

PGIC categories	Very much better	Much better	A little better	No change	A little worse	Much worse	Very much worse
vs. a little better				-0.3 (-1.7, 1.0)	-0.8 (-3.1, 1.5)	-4.8 (-9.2, -0.3)*	1.7 (-2.2, 5.5)
vs. no change					-0.5 (-3.0, 2.0)	-4.5 (-9.0, 0.1)	2.0 (-2.0, 6.0)
vs. a little worse						-4.0 (-8.9, 1.0)	2.5 (-1.9, 6.9)
vs. much worse							6.5 (0.6, 12.3)*

*p <0.05, ** p <0.01, *** p <0.001, **** p <0.0001. The pairwise LSMD (CI) and p-values were adjusted using Scheffe's correction

CI confidence interval, *LSM* least square mean, *LSMD* least square mean difference, *NRS* Numeric Rating Scale, *PGIC* Patient Global Impression of Change, *SD* standard deviation, *SE* standard error

Table S11 Responsiveness of the Urgency NRS by IBDQ and CDAI anchors at Weeks 12 and 52

Anchors	Urgency NRS score change from Baseline to Week 12			Urgency NRS score change from Baseline to Week 52		
	N	LSM (SE)	LSMD (CI)	N	LSM (SE)	LSMD (CI)
IBDQ Bowel Symptom domain response						
≥8-point increase	672	-3.0 (0.1)	-1.9 (-2.2, -1.6)****	681	-4.0 (0.1)	-1.8 (-2.2, -1.4)****
<8-point increase	332	-1.1 (0.1)		153	-2.2 (0.2)	
IBDQ response						
Yes: ≥16 point increase	704	-3.0 (0.1)	-1.9 (-2.2, -1.6)****	697	-4.0 (0.1)	-1.9 (-2.3, -1.5)****
No: <16 point increase	300	-1.1 (0.1)		137	-2.0 (0.2)	
IBDQ remission						
Yes: ≥170	495	-3.3 (0.1)	-1.8 (-2.1, -1.5)****	565	-4.3 (0.1)	-1.9 (-2.2, -1.6)****
No: <170	513	-1.5 (0.1)		271	-2.3 (0.1)	
CDAI response						
Yes	608	-3.5 (0.1)	-2.8 (-3.1, -2.5)****	710	-4.2 (0.1)	-3.1 (-3.5, -2.7)****
No	379	-0.7 (0.1)		129	-1.0 (0.2)	
CDAI remission						
Yes: <150	379	-4.0 (0.1)	-2.6 (-2.9, -2.4)****	536	-4.6 (0.1)	-2.5 (-2.8, -2.2)****
No: ≥150	631	-1.4 (0.1)		317	-2.1 (0.1)	

****All pairwise comparisons between groups reached a significance level of $p < 0.0001$

CDAI Crohn's Disease Activity Index, *CI* confidence interval, *LSM* least square mean, *LSMD* least square mean difference, *IBDQ* Inflammatory Bowel Disease Questionnaire, *NRS* Numeric Rating Scale, *SD* standard deviation, *SE* standard error

Table S12 Anchor-based estimates (supplemental anchors) for change in Urgency NRS from Baseline to Weeks 12 and 52

Anchors	Point change in Urgency NRS from Baseline to Week 12							Point change in Urgency NRS from Baseline to Week 52						
	N	Mean (SD)	Percentile					N	Mean (SD)	Percentile				
			10 th	25 th (Q1)	50 th (Q2)	75 th (Q3)	90 th			10 th	25 th (Q1)	50 th (Q2)	75 th (Q3)	90 th
IBDQ item 1 (bowel movement frequency) change														
≥4-point increase	277	-3.7 (2.6)	-7.0	-5.4	-3.7	-1.7	-0.4	280	-4.7 (2.7)	-8.1	-6.7	-4.9	-2.9	-1.0
3-point increase	174	-2.9 (2.5)	-6.1	-4.9	-2.9	-1.1	0.0	168	-3.8 (2.5)	-7.0	-5.4	-4.1	-2.0	-0.6
2-point increase	136	-2.4 (2.0)	-5.0	-3.6	-2.3	-0.6	0.0	116	-3.4 (2.2)	-6.3	-5.1	-3.4	-1.9	-0.6
1-point increase	158	-1.6 (2.0)	-4.6	-3.0	-1.3	-0.3	0.7	121	-2.8 (2.5)	-6.0	-4.1	-2.9	-0.7	0.0
No change	155	-1.4 (2.2)	-4.4	-2.6	-1.0	0.0	1.0	89	-2.4 (2.6)	-5.4	-4.4	-2.3	-1.0	0.4
≥1-point decrease	104	-0.8 (2.3)	-4.6	-1.7	-0.3	0.5	2.0	59	-2.0 (2.7)	-6.0	-4.0	-1.9	0.0	1.3
CDAI clinical response														
≥100-point increase	631	-3.4 (2.4)	-6.6	-5.0	-3.3	-1.7	-0.4	723	-4.1 (2.5)	-7.3	-6.0	-4.1	-2.3	-0.9
<100-point increase	379	-0.6 (1.7)	-2.7	-1.6	-0.4	0.1	1.3	129	-0.9 (2.1)	-4.3	-2.1	-0.8	0.3	1.6
IBDQ Bowel Symptom domain response														
≥8-point increase	672	-3.1 (2.5)	-6.4	-4.9	-2.9	-1.3	0.0	680	-4.0 (2.63)	-7.4	-6.0	-4.1	-2.0	-0.6
<8-point increase	332	-1.1 (2.1)	-4.1	-2.2	-0.6	0.0	1.1	153	-1.9 (2.33)	-4.9	-3.4	-1.7	-0.3	0.9

CDAI Crohn's Disease Activity Index, *IBDQ* Inflammatory Bowel Disease Questionnaire, *NRS* Numeric Rating Scale, *Q* quartile, *SD* standard deviation

Table S13 Anchor-based estimates (supplemental anchors) for Urgency NRS scores at Weeks 12 and 52

Anchors	Urgency NRS score at Week 12							Urgency NRS score at Week 52						
	N	Mean (SD)	10 th	Percentile				N	Mean (SD)	10 th	Percentile			
				25 th (Q1)	50 th (Q2)	75 th (Q3)	90 th				25 th (Q1)	50 th (Q2)	75 th (Q3)	90 th
IBDQ item 1 (bowel movement frequency)														
7=Normal, no increase in frequency of bowel movements	447	3.1 (2.5)	0.0	1.0	3.0	4.9	6.9	461	2.1 (2.1)	0.0	0.1	1.4	3.0	5.0
6=Slight increase in frequency of bowel movements	166	3.8 (2.4)	1.0	2.0	3.2	5.7	7.1	148	3.2 (2.2)	0.4	1.7	2.9	4.4	6.4
5=Some increase in frequency of bowel movements	99	4.2 (2.3)	1.0	2.7	4.1	5.7	7.2	77	3.4 (2.0)	0.4	2.1	3.6	4.3	6.4
4=Moderate increase in frequency of bowel movements	108	5.1 (2.4)	1.6	3.4	5.1	6.9	7.9	71	4.5 (2.6)	1.4	2.3	4.0	6.6	8.1
3=Very frequent	122	6.5 (2.2)	3.7	5.3	6.9	8.0	8.9	50	5.7 (2.7)	2.0	3.4	6.1	8.4	9.0
2=Extremely frequent	46	6.9 (2.4)	2.9	5.6	7.6	8.9	10.0	11	4.7 (4.1)	0.0	0.6	3.1	8.4	10.0
1=Bowel movements as or more frequent than they have ever been	21	6.2 (3.1)	1.0	4.6	7.7	8.1	9.6	17	4.5 (3.1)	1.0	2.0	4.3	6.1	9.6
IBDQ remission														
Yes: ≥170	495	3.1 (2.3)	0.0	1.1	2.7	4.6	6.4	564	2.2 (2.1)	0.0	0.4	1.8	3.3	5.1

No: <170	514	5.3 (2.7)	1.3	3.3	5.6	7.3	8.6	271	4.3 (2.6)	1.0	2.3	4.0	6.4	8.3
CDAI remission														
Yes: <150	608	3.1 (2.5)	0.0	1.1	2.7	4.7	6.9	709	2.4 (2.2)	0.0	0.7	2.0	3.6	5.2
No: ≥150	379	5.8 (2.3)	2.7	4.3	6.0	7.6	8.7	129	5.5 (2.5)	2.1	3.4	5.6	7.4	8.7

CDAI Crohn's Disease Activity Index, *IBDQ* Inflammatory Bowel Disease Questionnaire, *NRS* Numeric Rating Scale, *Q* quartile, *SD* standard deviation

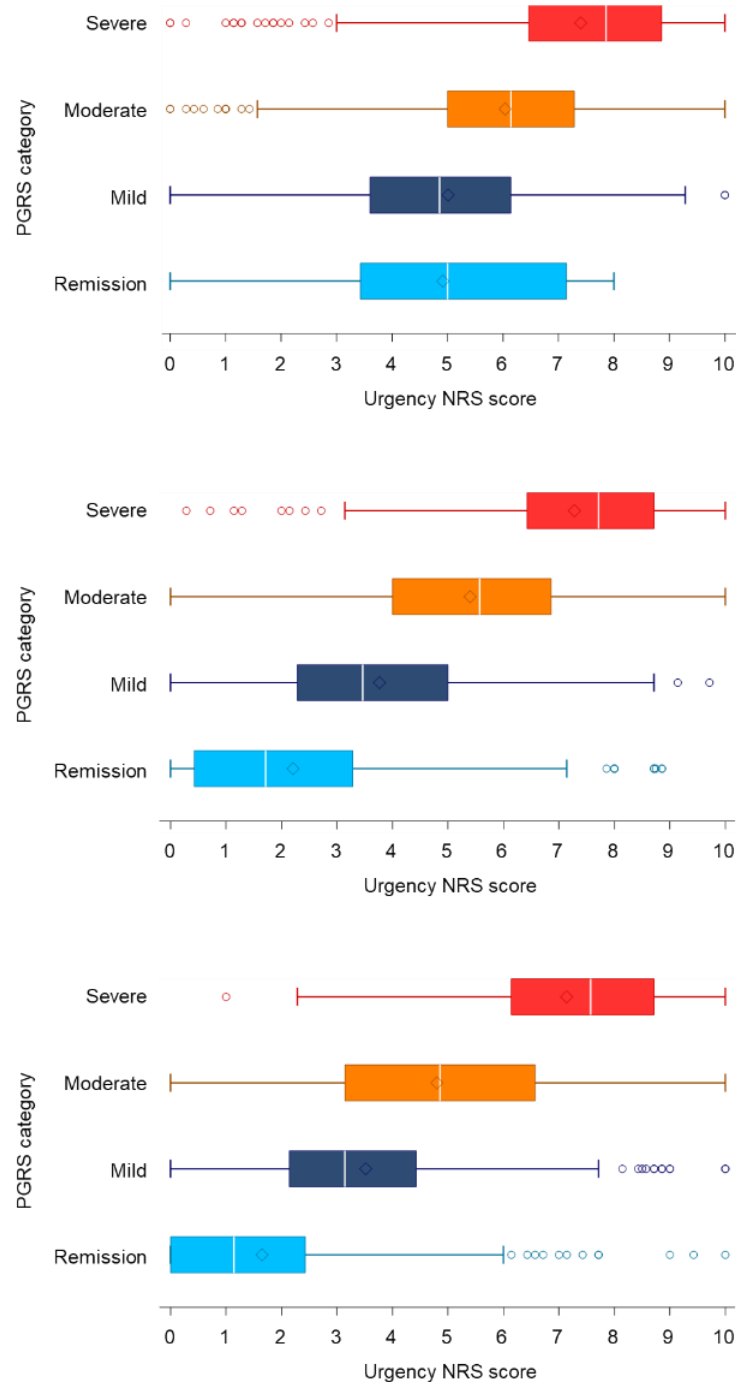


Fig. S1 Urgency NRS score distribution by PGRS at Baseline (top), Week 12 (middle), and Week 52 (bottom)

The “remission” category includes PGRS “none” to “very mild” responses, and the “severe” category includes “severe” and “very severe” responses.

NRS Numeric Rating Scale, PGRS Patient Global Rating of Severity

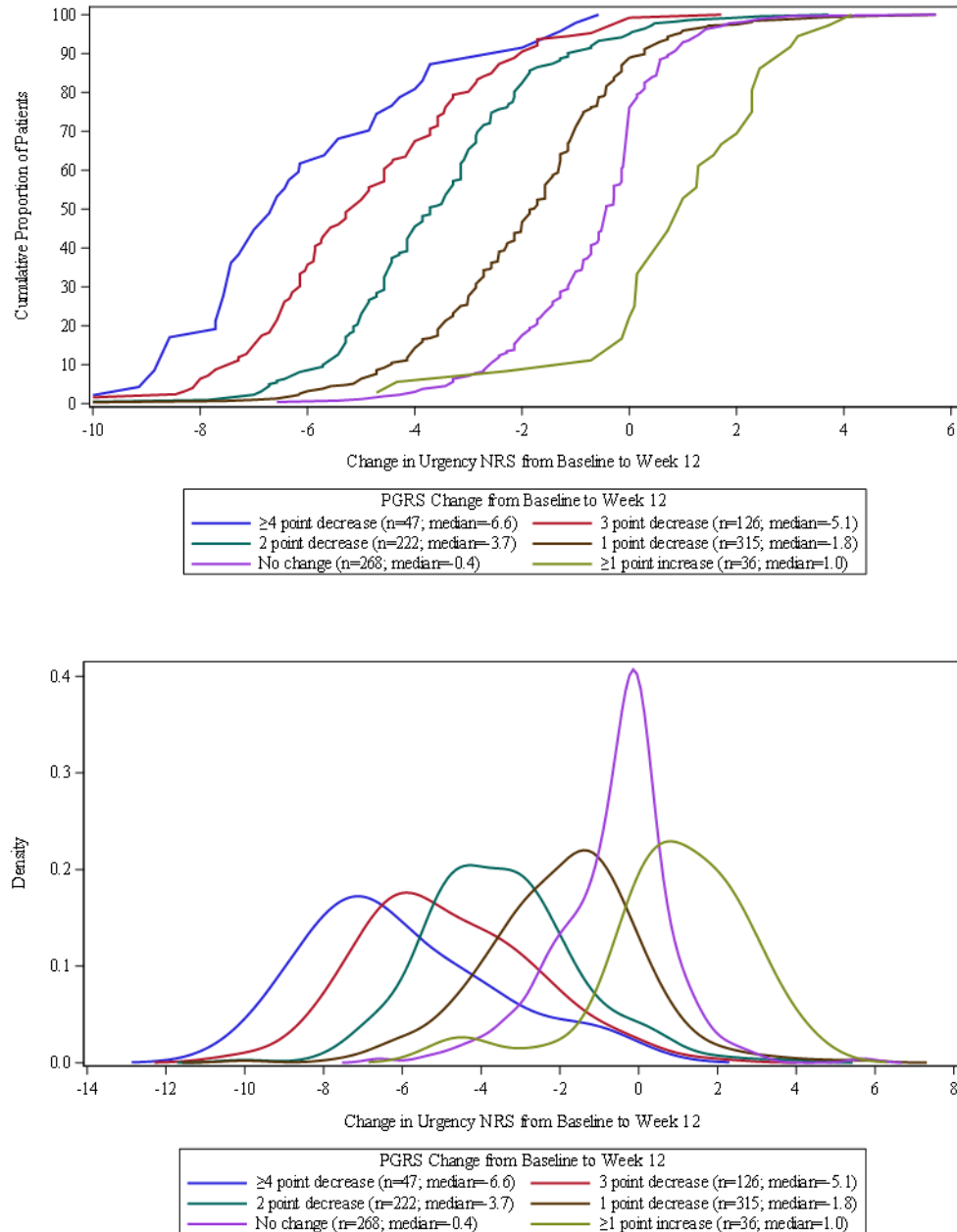


Fig. S2 CDF (top) and PDF (bottom) of Urgency NRS score change by PGRS at Week 12

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGRS* Patient Global Rating of Severity

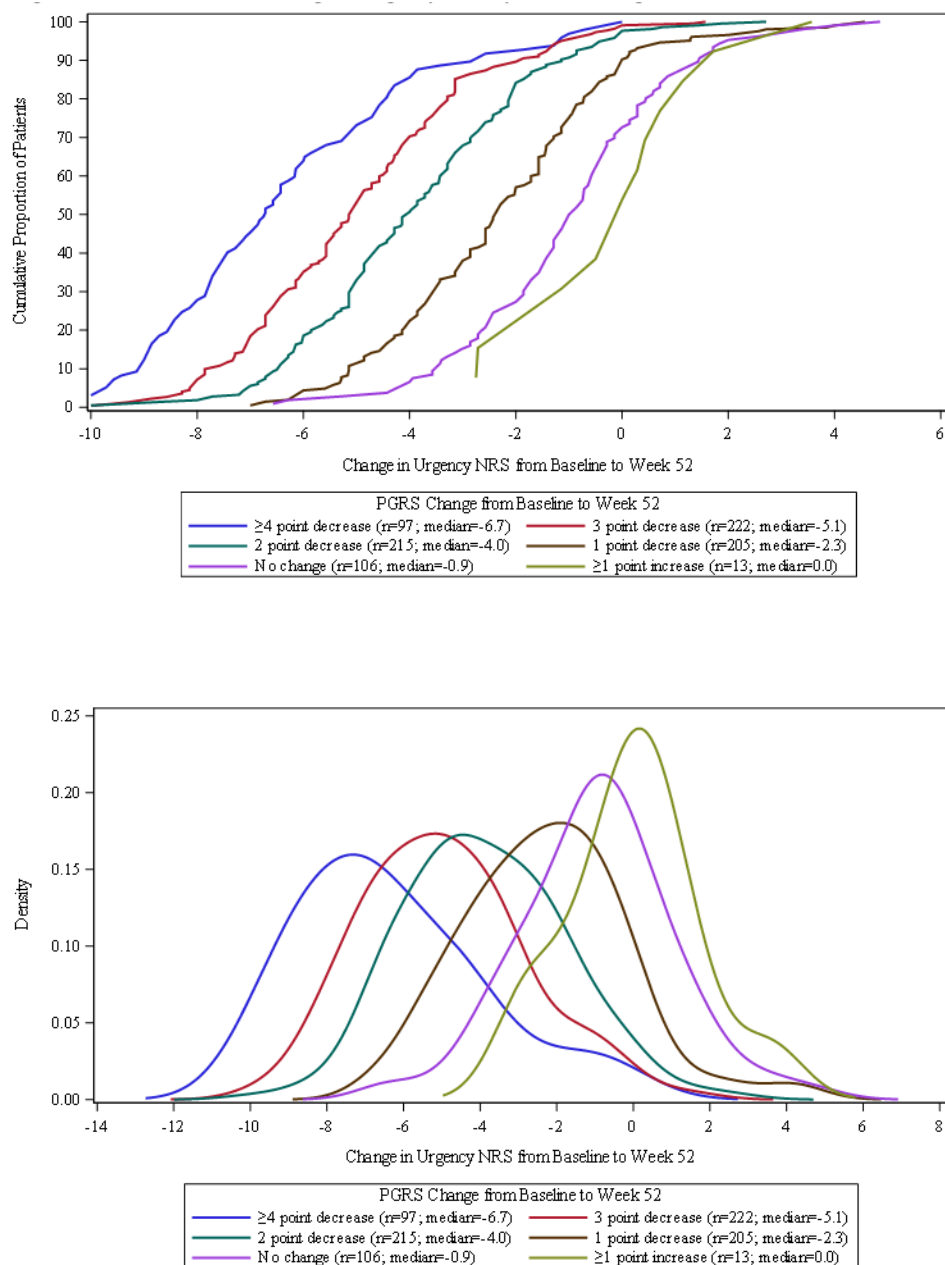


Fig. S3 CDF (top) and PDF (bottom) of Urgency NRS score change by PGRS at Week 52

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGRS* Patient Global Rating of Severity

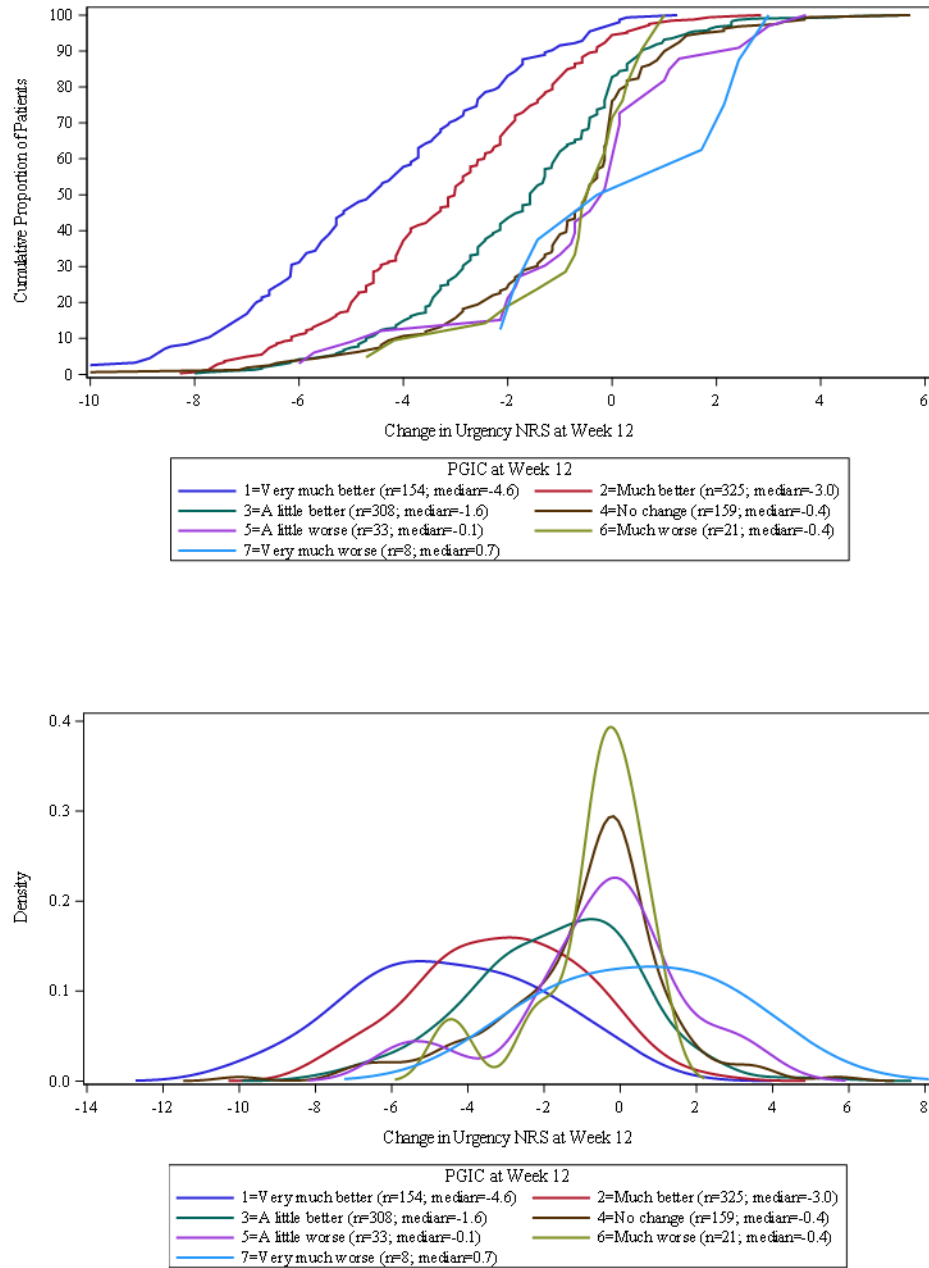


Fig. S4 CDF (top) and PDF (bottom) of Urgency NRS score change by PGIC at Week 12

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGIC* Patient Global Impression of Change

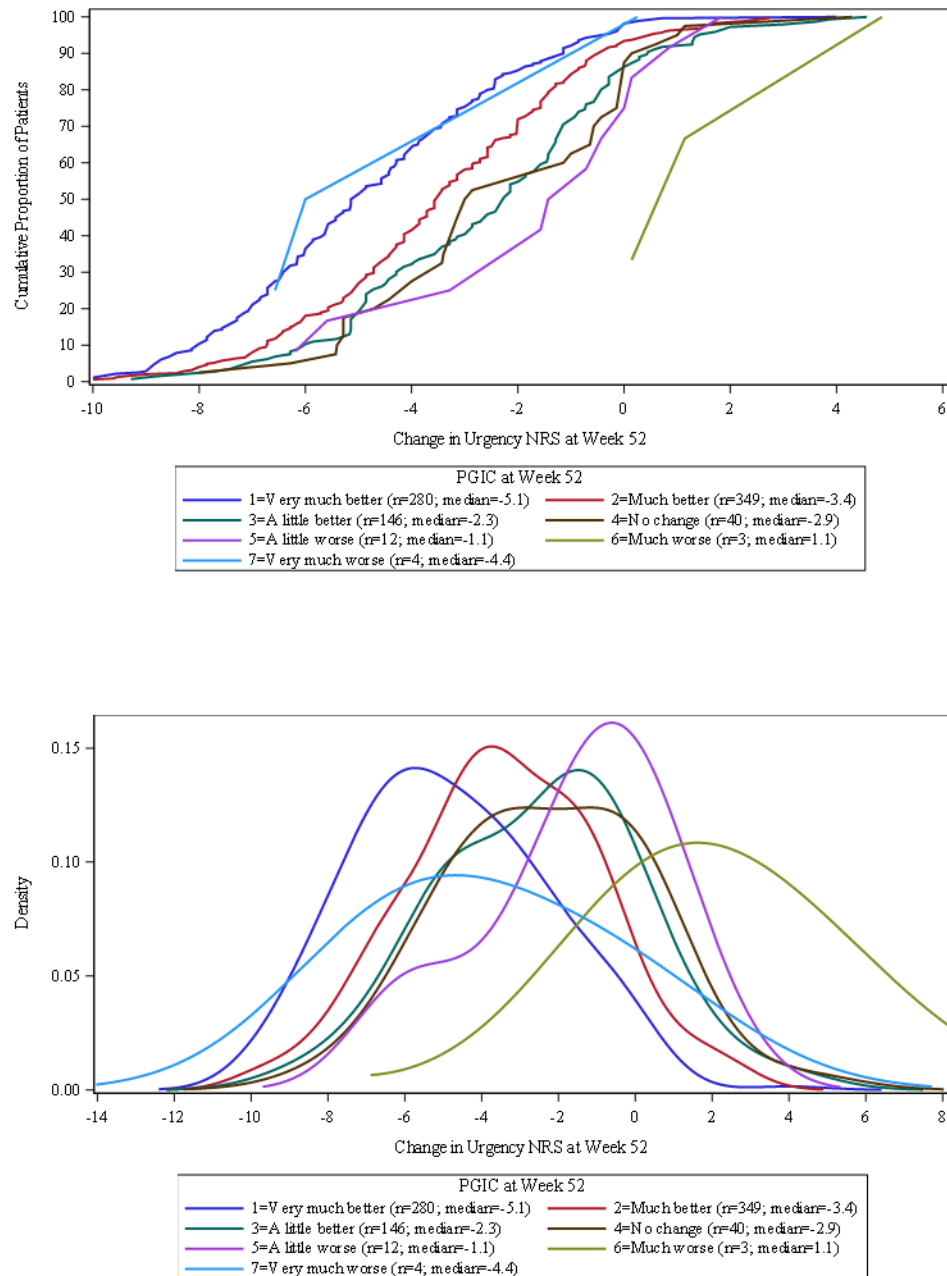


Fig. S5 CDF (top) and PDF (bottom) of Urgency NRS score change by PGIC at Week 52

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGIC* Patient Global Impression of Change

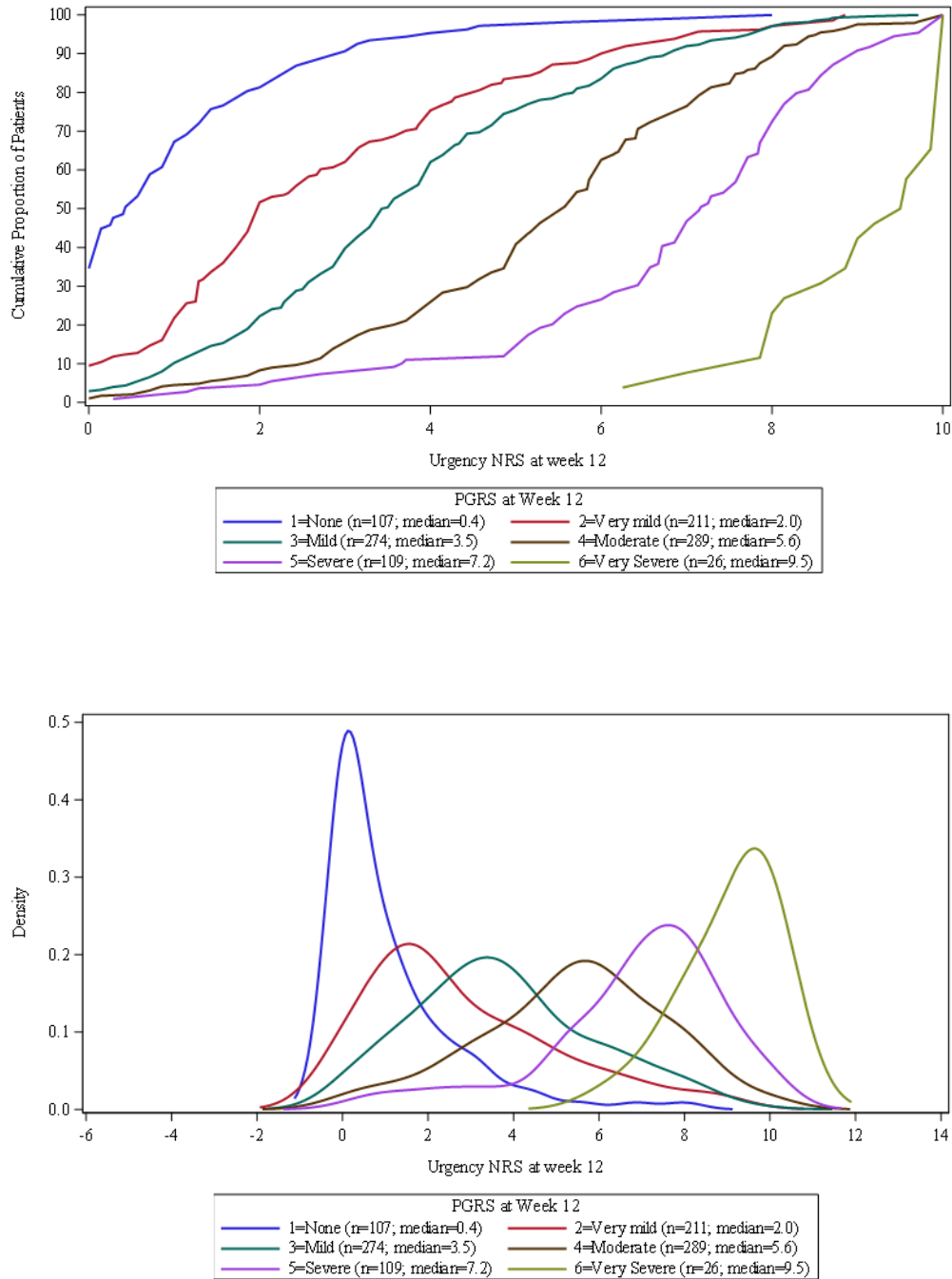


Fig. S6 CDF (top) and PDF (bottom) of Urgency NRS by PGRS at Week 12

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGRS* Patient Global Rating of Severity

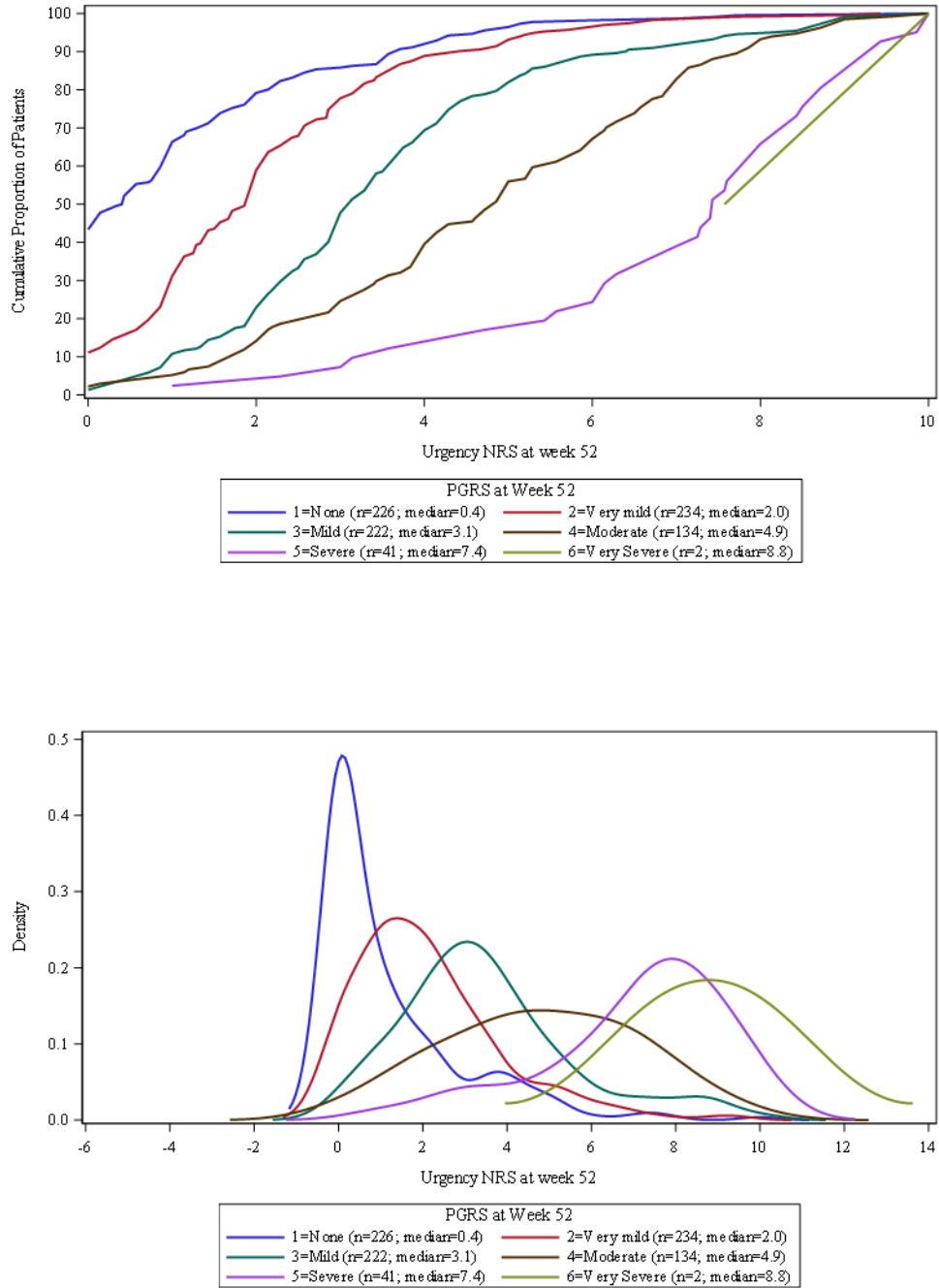


Fig. S7 CDF (top) and PDF (bottom) of Urgency NRS by PGRS at Week 52

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGRS* Patient Global Rating of Severity

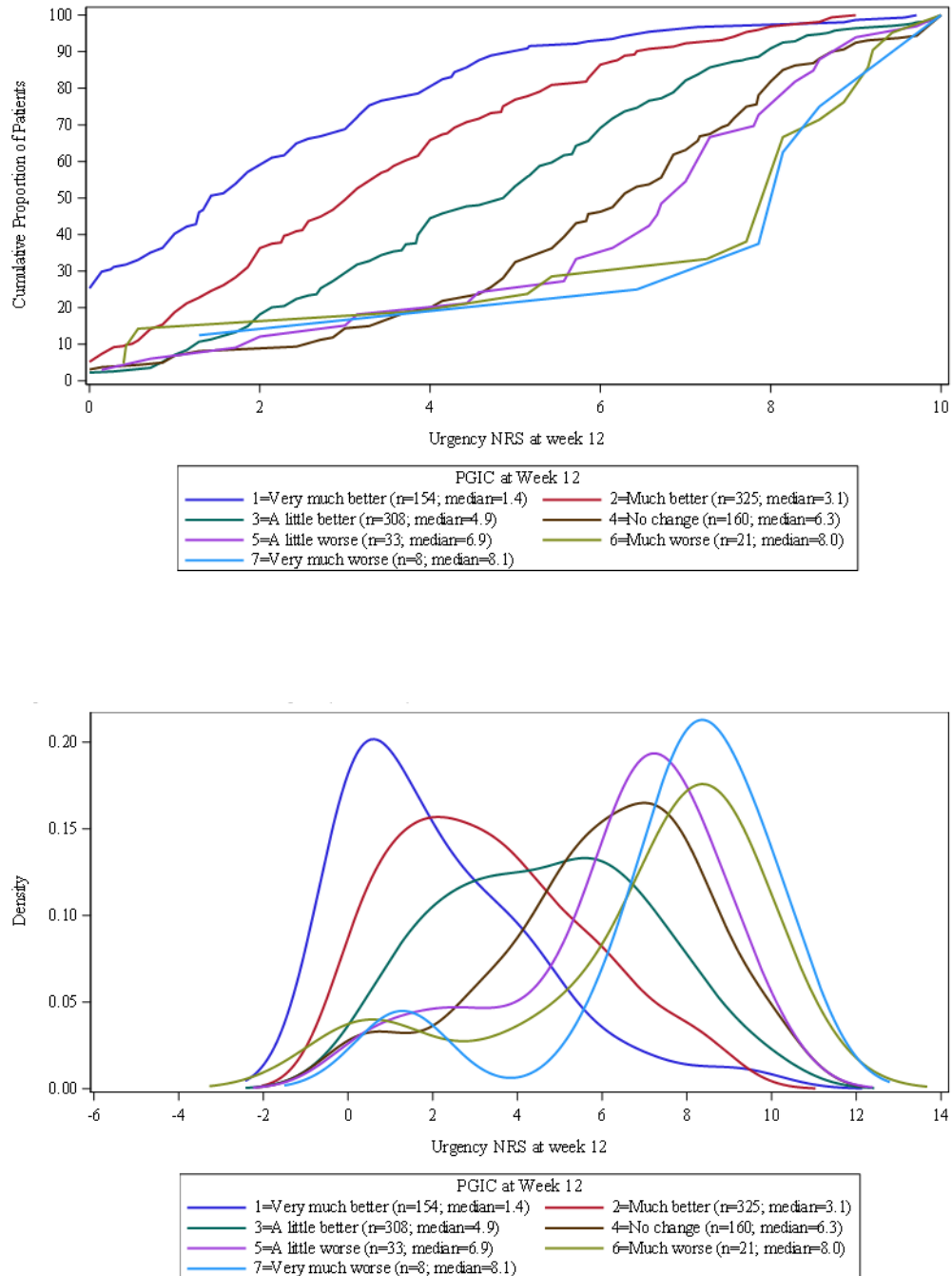


Fig. S8 CDF (top) and PDF (bottom) of Urgency NRS by PGIC at Week 12

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGIC* Patient Global Impression of Change

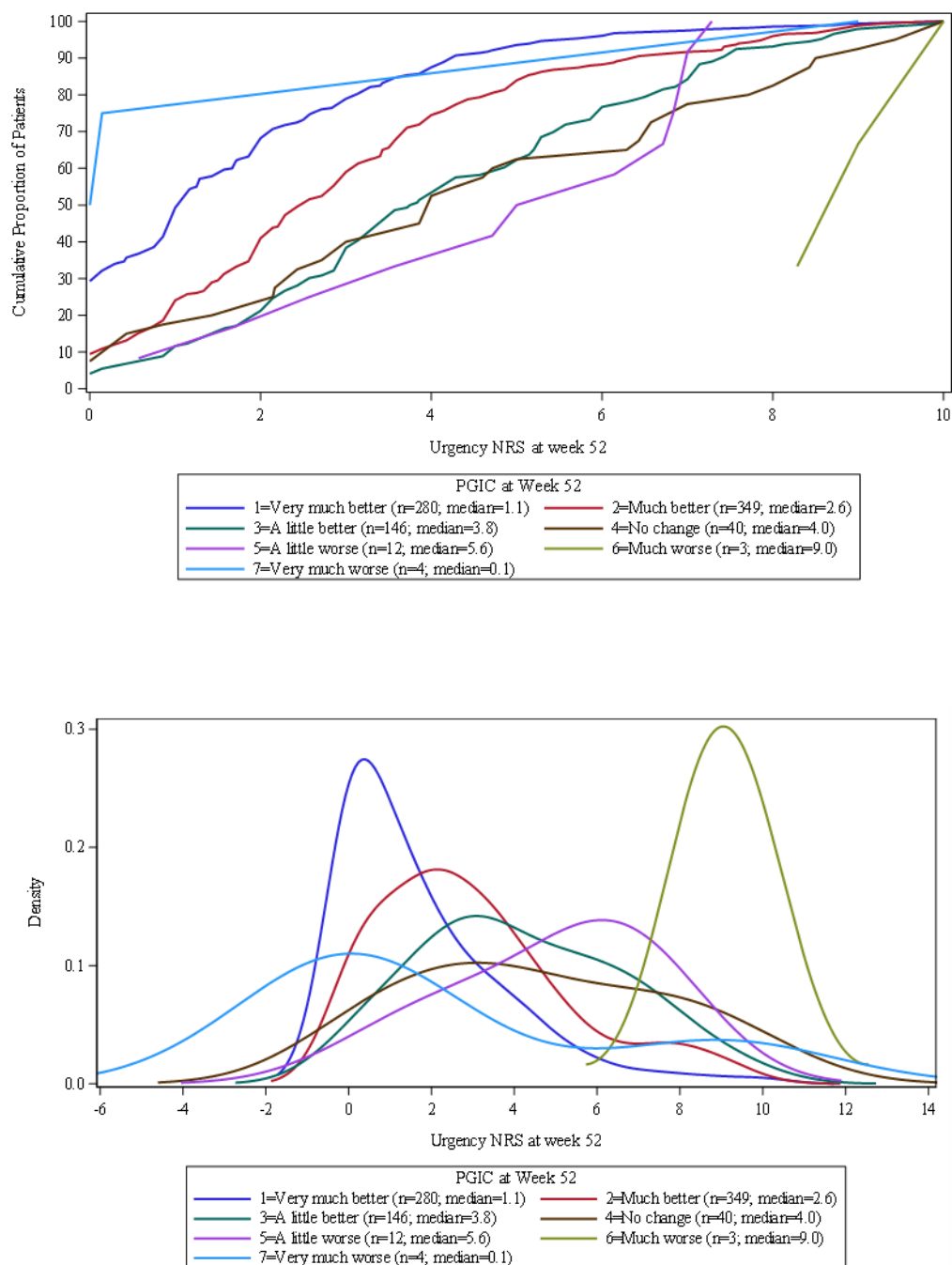


Fig. S9 CDF (top) and PDF (bottom) of Urgency NRS by PGIC at Week 52

CDF Cumulative Distribution Function, *NRS* Numeric Rating Scale, *PDF* Probability Density Function, *PGIC* Patient Global Impression of Change