2818

Real-World Patient Characteristics, Treatment Patterns, and Outcomes among Relapsed/Refractory Multiple Myeloma Patients Receiving talquetamab-tgvs

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Key Takeaways

- **Strong real-world treatment response**: TAL shows strong real-world effectiveness in RRMM patients, with outcomes consistent with pivotal trials. Real-world overall response rate (rwORR) was 86.4% in the USPI cohort; 43.2% achieved VGPR or better.
- **Community practices play a major role**: Approximately one-fifth of the USPI cohort initiated TAL in the community setting; and the majority (>65%) of those who initiated in academic setting were referred back to the community for management.
- **Mild adverse events**: Most adverse events (CRS, ICANs, infections) were grade 2 or lower and were successfully managed without treatment discontinuation, supporting the tolerability of TAL in routine practice.
- However, these were observed over a short follow-up (3.5 months in the USPI Cohort) and need cautious interpretation.

Conclusions

- **This real-world study of patients with RRMM treated with TAL, including those managed in community settings, demonstrated a strong treatment response, and mild and manageable adverse events.**
- **Theses results support the use of TAL as an effective treatment option for RRMM patients in community settings, expanding access beyond academic centers.**

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Correspondence and Disclosures

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Introduction and Objective

- Multiple myeloma (MM), the second most common hematologic cancer, is estimated to have 36,110 new United States (US) cases in 2025.[1] Despite therapeutic advances, patients with relapsed or refractory multiple myeloma (RRMM), often still experience limited treatment options and ongoing clinical challenges.
- On 9 August 2023, the Food and Drug Administration gave accelerated approval to talquetamab-tgvs (TAL) for treatment of adults with RRMM after at least four prior lines of therapies (LOT), including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (i.e., triple class exposed [TCE]).[2]
- Talquetamab-tgvs uses two or three step-up doses prior to full treatment doses (mg/kg: 0.4 weekly [QW] or 0.8 biweekly [Q2W]) to mitigate cytokine release syndrome (CRS).[3]
- The MonumenTAL-1 trial showed an overall response rate (ORR) of ~73% for both doses.[4]
  - Median duration of response (DOR): 9.5 months (0.4 mg/kg); 16.9 months (0.8 mg/kg)
  - 85% maintained response ≥9 months
- **The objective of this study was to examine real-world treatment patterns and outcomes in RRMM patients treated with TAL including those managed in community settings, in which evidence is limited.**

Methods and Materials

- This retrospective, observational, multi-site, medical chart review study examined data of adults ≥18 years with confirmed RRMM who were predominantly managed in the community setting and initiated TAL on or after 9 August 2023, outside of the clinical trial setting. Patients were required to have at least one month of follow up after TAL initiation. Data collection occurred between 21 April 2025 and 14 May 2025.
- Physicians from the Cardinal Health Oncology Provider Extended Network (OPEN) identified patients meeting the study selection criteria above and abstracted de-identified data from patients' electronic medical records into electronic case report forms.
- Data were summarized using descriptive statistics for all patients and for a US Prescribing Information (USPI) cohort.
  - USPI Cohort: Triple class exposed, initiated TAL as monotherapy after at least four prior LOTs, non-bridging to CAR-T, who only received SUD in an inpatient setting and did not switch to less frequent dosing, pursuant to the USPI.

Results

Physician and Practice Characteristics

- Overall, 25 physicians participated in the study, with a median of 14.8 years in practice. Majority (72.0%) practiced in the community setting. The most common (40.0%) primary practice setting reported was large private community practices (>10 physicians). They were geographically dispersed across the US.

Patient Demographics and Clinical Characteristics

- Of the 176 patients included in the study, only 98 (55.7%) patients met the USPI cohort criteria (**Figure 1**).
- Baseline characteristics are summarized in **Table 1**.
- Majority (72.2%) of all patients were managed in the community setting. In the USPI cohort, the median time from RRMM diagnosis to TAL initiation was 34.3 months and the median follow-up from TAL initiation was 3.5 (IQR: 2.3-5.9) months.
- At the time of TAL initiation, most USPI patients (84.7%) had an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; high-risk cytogenetics were present in 57.0%; and lytic bone lesions was observed in 69.4% (**Table 1**).

Treatment Patterns

- Prior to TAL, all patients (n=176) received systemic therapy.
- In the USPI cohort, 60.2% were B-cell maturation antigen (BCMA) exposed prior to TAL – 36.7% received chimeric antigen receptor (CAR) T-cell therapy, 22.5% received bispecific antibodies and 1.0% received antibody-drug conjugates (ADCs).
- Top primary reasons for initiating TAL were clinical evidence (89.8%), disease progression (50.0%) and BCMA exposure (38.8%). and median duration of treatment (DOT) was 5.6 months.
- Across all patients, 99.0% (n=175/176) received the full treatment dose (FTD) of TAL. Within the USPI cohort, 78.4%(n=76/97) initiated TAL in the academic setting, however 65.8% of these patients were referred back to the community setting at completion of FTD.
- Among all patients, 25% (n=44/176) discontinued TAL and in the USPI cohort, 17.3% (n=17/98) discontinued TAL. Reasons for discontinuation in the USPI cohort included disease progression (8.2%), death (4.1%), patient choice (3.1%), adverse events (2.0%), comorbidities (1.0%) and ECOG-PS (1.0%). Only 1 patient initiated a new LOT post-TAL with a median time to next treatment (TTNT) from TAL initiation of 10.5 months (**Table 2**).

Outcomes

- Among all patients at the time of data collection, 86.9% were still alive, the majority (75.0%) were still receiving TAL and the median follow-up from TAL initiation was 3.9 (IQR: 2.3 – 8.1) months.
- The real-world overall response rate (rwORR) for TAL in all patients was 81.0% (95% CI [73.6 – 87.0]) among 119 response-evaluable patients and 86.4% (95% CI [77.4 – 92.8]) among 76 response-evaluable patients in the USPI cohort. A very good partial response (VGPR) or better was achieved by 38.8% of all patients and 43.2% of the USPI cohort. The rwORR for BCMA exposed and BCMA naïve subgroups in the USPI cohort was 83.9% (95% CI [71.7 – 92.4]) and 90.6% (95% CI [75.0 – 98.0]) respectively (**Figure 2**).
- The median real-world duration of response (rwDOR) was 10.8 months for both all patients and the USPI cohort (**Figure 3a and Figure 3b**).
- At six months post TAL initiation, for all patients, the overall survival (OS) and progression free survival (PFS) was 85.9% (95% CI [77.8 – 91.2]) and 82.5% (95% CI [73.6 – 88.7]). In the USPI cohort, the six-month OS and PFS was 90.6% (95% CI [78.9 – 96.0]) and 87.1% (95% CI [72.8 – 94.1]).

Adverse Events

- In all patients, cytokine release syndrome (CRS) occurred in 34.7%, immune effector cell-associated neurotoxicity syndrome (ICANS) in 6.3%, infections in 15.3% patients, and 29.0% experienced adverse events of special interest (AESI) including dry mouth, dysgeusia, dysphagia, fatigue and loss of appetite.
- In the USPI cohort, CRS occurred in 29.6% and all CRS was grade ≤2, with 79.3% being grade 1. ICANS occurred in 6.1% and all ICANS were grade 1. Infection occurred in 17.3% and 88.2% of infections was grade ≤2. AESI occurred in 17.4% and all were grade ≤2 (**Table 3**).

Table 1. Patient Demographics and Clinical Characteristics

	All Patients N=176	USPI Cohort n=98
Median age at initial RRMM diagnosis in years (IQR)	66.3 (61.0 – 70.7)	66.0 (61.2 – 69.5)
Age group ≥75	19 (10.8)	9 (9.2)
Male, n (%)	105 (59.7)	61 (62.3)
Race (n, %)*		
Black or African-American	41 (23.3)	31 (31.6)
White	124 (70.5)	62 (63.3)
Other	11 (6.3)	5 (5.1)
Revised International Staging System (R-ISS) used, (n,%)	140 (79.6)	77 (78.6)
Stage III	64 (45.7)	40 (51.9)
Prior Stem Cell Transplant	43 (24.4)	22 (22.5)
Median follow-up from initiation of talquetamab-tgvs (months; IQR)	3.9 (2.3 – 8.1)	3.5 (2.3 – 5.9)
Median time from RRMM diagnosis to initiation of talquetamab-tgvs initiation (months; IQR)	29.1 (17.1 – 39.2)	34.3 (22.9 – 42.9)
High cytogenic risk among patient with cytogenic test done at the time of MM diagnosis, n (%)	86 (51.2)	53 (57.0)
Lytic bone lesions present, n (%)	113 (64.2)	68 (69.4)
Extramedullary plasmacytomas present, n (%)	8 (5.1)	5 (5.1)
ECOG Performance Status at initiation of talquetamab-tgvs, n (%)		
0-1	129 (73.3)	83 (84.7)
≥2	46 (26.7)	15 (15.3)

*Categories of response not mutually exclusive

Table 2. Treatment Patterns

	All Patients N=176	USPI Cohort n=98
Treatment History		
≥4 prior lines of therapy, n (%)	108 (61.4)	98 (100)
Prior triple class exposure, n (%)	174 (98.9)	98 (100)
Prior radiation therapy (n, %)	27 (15.3)	4 (4.1)
Prior BCMA (n, %)		
BCMA-targeted Antibody-Drug Conjugate only	1 (0.6)	1 (1.0)
CAR T-Cell Therapy only	60 (34.1)	36 (36.7)
BCMA-targeted Antibody-Drug Conjugate and CAR T-Cell Therapy	1 (0.6)	0 (0.0)
Bispecific Antibodies	30 (17.1)	22 (22.5)
Median treatment-free interval prior to TAL initiation (n, %)	0.7 (0.4 – 2.0)	1 (0.5 – 2.0)
Treatment Pattern		
TAL use as Bridging therapy (N, %)	4 (2.3)	0 (0.0)
TAL use as Mono vs combination therapy (n, %)	173 (98.3)	98 (100)
Initial dosing schedule (n, %)		
0.4 mg/kg QW (weekly)	86 (50.6)	55 (57.3)
0.8 mg/kg Q2W (bi-weekly)	84 (49.4)	41 (42.7)
Reasons for initiating talquetamab-tgvs (n, %)*		
Clinical evidence	129 (73.3)	88 (89.8)
Disease progression	95 (54.0)	45 (50.0)
BCMA exposure	69 (39.2)	38 (38.8)
Patients who received full treatment dose of talquetamab-tgvs (n, %)	175 (99.4)	97 (99.0)
Median duration of treatment for TAL, among those who discontinued (months; IQR)	3.7 (1.5 – 7.9)	5.6 (3.4 – 8.0)
Care setting were the patients-initiated treatment with talquetamab-tgvs, among those who completed FTD (n, %)		
Academic	124 (70.9)	76 (78.4)
Community	52 (29.1)	21 (21.7)
Patients who switched from Academic setting to community setting (n, %)	71 (57.3)	50 (65.8)
Patient discontinued therapy, yes (n, %)	44 (25.0)	17 (17.3)
Primary reason for discontinuation of talquetamab-tgvs (n, %)*		
Disease progression	19 (10.8)	8 (8.2)
Death	6 (3.4)	4 (4.1)
Patient choice	7 (4.0)	3 (3.1)
Adverse event	7 (4.0)	2 (2.0)
Others	12 (6.8)	2 (2.0)

*Categories of response not mutually exclusive

Table 3. Adverse Events

	All Patients N=176	USPI Cohort n=98
Cytokine Release Syndrome, n (%)	**61 (34.7)**	**29 (29.6)**
Grade 1	38 (21.6)	23 (23.5)
Grade 2	20 (11.4)	6 (6.1)
Grade 3	2 (1.1)	0 (0.0)
Missing/unknown	115 (65.3)	69 (70.4)
Immune Effector Cell-Associated Neurotoxicity Syndrome, n (%)	**11 (6.3)**	**6 (6.1)**
Grade 1	9 (5.1)	6 (6.1)
Grade 2	1 (0.6)	0 (0.0)
Grade 3	1 (0.6)	0 (0.0)
Missing/unknown	165 (93.8)	92 (93.9)
Infection, n (%)	**27 (15.3)**	**17 (17.3)**
Grade 1	9 (5.1)	7 (7.1)
Grade 2	12 (6.8)	8 (8.2)
Grade 3	5 (2.8)	1 (1.0)
Missing/unknown	1 (0.6)	1 (0.6)
G Protein-Coupled Receptor Class C Group 5 Member D-related AEs, n (%)	**51 (29.0)**	**17 (17.4)**
Dry Mouth	35 (19.9)	13 (13.3)
Dysgeusia	26 (14.8)	11 (11.2)
Dysphagia	4 (2.3)	2 (2.0)
Other: Fatigue, loss of appetite	1 (0.6)	0 (0.0)

Figure 1: USPI Cohort Attrition Chart

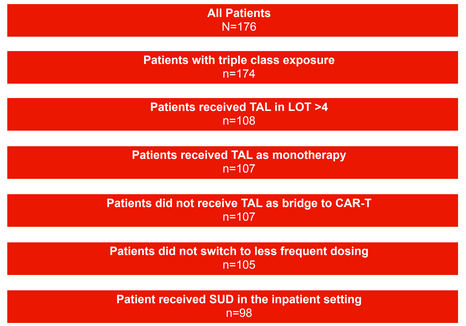


Figure 2: rwORR Based on Best Charted Response

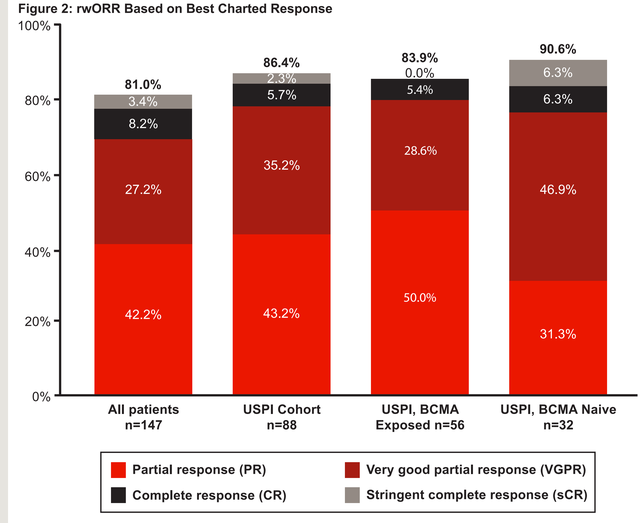


Figure 3: Duration of Response

Figure 3a. DOR – All Patients

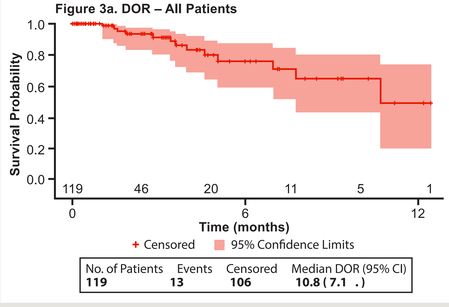
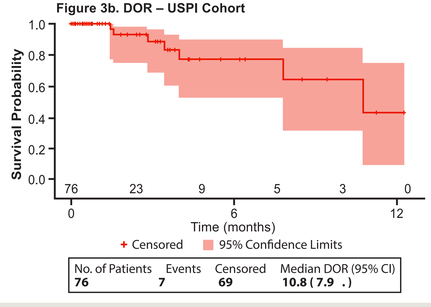


Figure 3b. DOR – USPI Cohort



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Multiple Myeloma

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