

Real-world safety outcomes and healthcare resource utilization (HCRU) during outpatient, inpatient, and hybrid step-up dosing (SUD) of teclistamab (Tec) and talquetamab (Tal): a chart review study

Cindy Varga^{1*}, Jack Khouri², David Oveisi³, Sibel Blau⁴, Baylee Bryan⁵, Gilbert Ko⁶, Santosh Gautam⁶, Niodita Gupta-Werner⁶, Xinke Zhang⁶, Fan Mu⁷, Ryan Simpson⁷, Joshua Young⁷, Tonya LeBlanc⁶, Shuchita Kaila⁶, Douglas Sborov⁵, Lisa Raff⁶

¹ Atrium Health, Charlotte, NC, USA; ² Cleveland Clinic, Cleveland, OH, USA; ³ Cedars-Sinai, Los Angeles, CA, USA; ⁴ ONCare Alliance, Tacoma, WA, USA; ⁵ Huntsman Cancer Institute, Salt Lake City, UT, USA; ⁶ Johnson & Johnson, Horsham, PA, USA; ⁷ Analysis Group, Inc., Boston, MA, USA; ⁸ OneOncology, Chicago, IL, USA

*Presenting author

Key Takeaway


Outpatient (OP) step-up dosing (SUD) models for administering teclistamab (Tec) or talquetamab (Tal) to patients with relapsed or refractory multiple myeloma (RRMM) are feasible, can be safely implemented, and are resource-sparing with appropriate patient selection.

Conclusions

Rates of cytokine release syndrome (CRS; mainly grades 1 or 2) and immune effector cell associated neurotoxicity syndrome (ICANS) were numerically lower among OP compared to IP SUD patients in this study.

On average, patients with OP SUD had 9 fewer hospitalized days as compared to IP SUD patients. OP SUD can help in reducing HCRU while enabling safe initiation of Tec and Tal.

OP SUD patients receiving Tec or Tal were older than inpatient (IP) and hybrid SUD patients yet had fewer median prior lines of therapy and lower Eastern Cooperative Oncology Group (ECOG) score, indicating that providers are selective when identifying patients for OP SUD.



Please scan QR code

Poster

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way. Additional information is provided here:
<https://www.congresshub.com/Oncoology/IMS2025/Teclistamab/Varga>

Acknowledgments
The authors thank Zhenyi Cao, Calvin Plays, and Yan Wang, employees of Analysis Group, Inc., for conducting data cleaning and statistical analysis. The authors thank Saurabh Patel, an employee of Johnson & Johnson during the conduct of this study, for insights on study design and research dissemination.

Disclosures
CV conducts research as part of ARCELIX, K36 and serves in advisory role for Janssen. JK serves in consulting and advisory roles for J&J, Prothena, Legend Biotech, Kite, Ascentage, Karyopharm, and GPCR therapeutics. DO has served on the speaker's bureau for J&J and has done consulting via advisory board for Pfizer and via steering committee for BMS. SB declares husband is Founder (CEO) of AllCare and is a shareholder of P1 Trials, LLC. GK, SG, NGW, XZ, TL, and SK are employees of Johnson & Johnson and may own shares and/or its stock options. FM, RS, and JY are employees of Analysis Group, Inc., which received funding from Johnson & Johnson for conducting this research. DS conducts research with Pfizer and Regeneron and advises and consults with Sanofi, Janssen, Pfizer, Abbvie, GSK, BMS, Opna Bio, AstraZeneca, Arcsino, Regeneron BB and LH have nothing to disclose.

Introduction

- Tec, a bispecific antibody (BsAb) targeting B-cell maturation antigen (BCMA) and CD3, and Tal, targeting GPRC5D and CD3 were first-in-class BsAbs approved in the United States (US) for the management of relapsed or refractory multiple myeloma (RRMM).
- Traditionally, SUD of Tec and Tal for RRMM has been conducted in inpatient (IP) settings to monitor for adverse events (AEs), such as cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS), after each SUD administration.^{1,2}
- Recent real-world studies have shown that practices are evolving to an outpatient (OP) SUD administration model to reduce HCRU and improve patient convenience while still safely initiating Tec or Tal.³⁻⁵
- This multi-site, real-world study described the patient characteristics, safety outcomes, and HCRU of Tec and Tal patients receiving SUD in OP, IP, and hybrid settings.

Results

Study sample

- As shown in **Table 1**, the median age at index for OP SUD patients was 75.0 years (IP: 68.8 years; hybrid: 66.5 years); OP SUD patients were 66.7% White and 28.6% Black (IP: 82.6% and 14.4%; hybrid: 75.0% and 16.2%).
- There were 23.8% of OP SUD patients that had ECOG score ≥2 (IP: 38.6%; hybrid: 26.4%) and 28.6% had high-risk cytogenetics⁶ (IP: 54.5%; hybrid: 55.9%).
- At index, 85.7% of OP SUD patients had serum measurable MM disease (IP: 73.5%; hybrid: 73.5%), a median of 40.0% plasma cells in bone marrow (IP: 60.0%; hybrid: 60.0%), and had received a median of 4 prior lines of treatment (IP: 6; hybrid: 5).
- For OP SUD patients, the median time from first MM diagnosis to the index date was 7.1 years (IP: 5.4; hybrid: 5.9) and median duration of follow-up after the index date was 4.8 months (IP: 9.9; hybrid: 7.9).
- All but 1 IP SUD Tec patient completed all SUD doses (SUD in progress at time of chart abstraction).

Table 1. Patient characteristics at index^a

	OP SUD N = 21	IP SUD N = 132	Hybrid SUD N = 68
Index treatment			
Teclistamab (Tec)	17 (81.0%)	93 (70.5%)	36 (52.9%)
Talquetamab (Tal)	4 (19.0%)	39 (29.5%)	32 (47.1%)
Age at index (years)			
Median (IQR)	75.0 (66.9, 82.4)	68.8 (61.8, 75.7)	66.5 (59.8, 72.2)
Male	12 (57.1%)	77 (58.3%)	39 (57.4%)
Race			
White	14 (66.7%)	109 (82.6%)	51 (75.0%)
Black/African American	6 (28.6%)	19 (14.4%)	11 (16.2%)
Other	1 (4.8%)	2 (1.5%)	2 (2.9%)
Unknown	0 (0.0%)	2 (1.5%)	4 (5.9%)
ECOG			
<2	16 (76.2%)	78 (59.1%)	49 (72.1%)
≥2	5 (23.8%)	51 (38.6%)	18 (26.5%)
Unknown	0 (0.0%)	3 (2.3%)	1 (1.5%)
Cytogenetic risk⁶			
High	6 (28.6%)	72 (54.5%)	38 (55.9%)
Standard	14 (66.7%)	44 (33.3%)	27 (39.7%)
Unknown	1 (4.8%)	16 (12.1%)	3 (4.4%)
MM disease type at index			
Serum measurable	18 (85.7%)	97 (73.5%)	50 (73.5%)
Serum free light chains only	2 (9.5%)	26 (19.7%)	11 (16.2%)
Plasma cell only	0 (0.0%)	6 (4.5%)	2 (2.9%)
Unknown	1 (4.8%)	3 (2.3%)	5 (7.4%)
Plasma cells in bone marrow at index (%)			
Median (IQR)	40.0 (20.0, 61.5)	60.0 (30.5, 80.0)	60.0 (28.0, 80.0)
Unknown	2 (9.5%)	9 (6.8%)	4 (5.9%)
Prior lines of treatment received			
Median (IQR)	4.0 (4.0, 5.0)	6.0 (4.0, 8.0)	5.0 (4.0, 6.0)
Years from first MM diagnosis to index			
Median (IQR)	7.1 (4.0, 8.7)	5.4 (2.6, 8.1)	5.9 (3.1, 8.1)

Abbreviations: ECOG, Eastern Cooperative Oncology Group; IP, inpatient; IQR, interquartile range; OP, outpatient; MM, multiple myeloma; SUD, step-up dosing; Tal, Talquetamab; Tec, Teclistamab.

Notes:

a. Demographic characteristics were evaluated at the index date (i.e., the date of the first Tec or Tal SUD). Clinical characteristics were evaluated using the assessment closest to and within 12 months prior to the index date. Disease history was evaluated from initial MM diagnosis to the index date.

b. High cytogenetic risk per Tan et al. (2025) was defined as having any of the following genetic abnormalities: del(17p), t(4;14), t(14;16), t(14;20), t(21 gain/ amplification).⁶

Limitations

- The number of patients in the OP SUD cohort is small, limiting the statistical power for conducting a formal comparative analysis across cohorts.
- The grades of ICANS events were not collected.
- There may be underreporting of outcomes due to the retrospective nature of this study.

Methods

Data source

- The study used deidentified data from the eMMPower consortium (PA-322), an ongoing, longitudinal, multi-site, real-world retrospective chart review study of patients with MM in the US (data collection cut-off date: 31 March 2025).

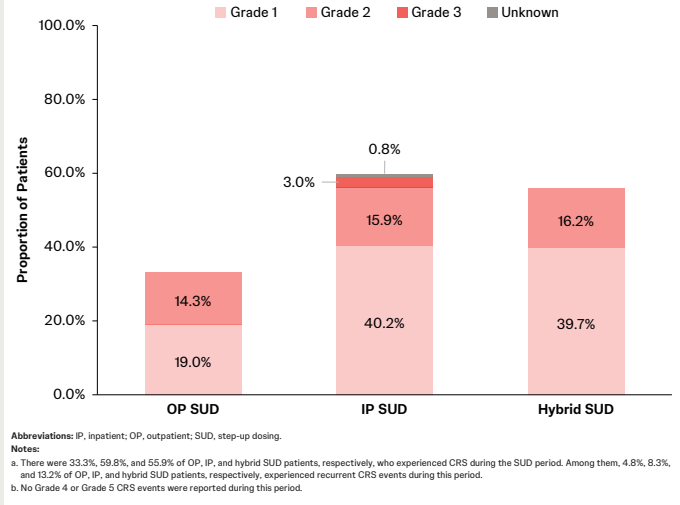
Study design

- Adults with RRMM initiating Tec or Tal monotherapy after the FDA approval date (25 Oct 2022 for Tec and 9 Aug 2023 for Tal) were included in this study. Patients receiving Tec or Tal in a clinical trial, as part of an expanded access program, or as a bridging therapy to CAR-T were excluded.
- Index date was defined as the first dose of Tec or Tal.

Safety outcomes

- During SUD, 7 (33.3%) OP SUD patients had CRS (IP: 79 [59.8%]; hybrid: 38 [55.9%]).
 - All CRS events were grades 1 or 2, with the exception of 4 grade 3 events (3.0%) among the IP SUD cohort (see **Figure 1**).
- No ICANS events were reported among OP SUD patients while 11.4% of the IP SUD cohort and 7.4% of the hybrid SUD cohort experienced ICANS during the SUD period (see **Table 2**).
- From SUD completion to 30 days post-treatment initiation, no OP SUD patients experienced CRS or ICANS; two grade 2 CRS events were reported (one among IP SUD and one among hybrid SUD patients) as well as 1 ICANS event was reported among hybrid SUD patients.
- Tocilizumab was used to treat CRS in IP and hybrid SUD cohorts (47.7% and 30.9% of patients, respectively); no OP SUD patients were treated with tocilizumab (see **Table 2**). One hybrid SUD patient was administered tocilizumab prophylactically for CRS.

Figure 1. Maximum CRS grade occurring during the SUD period^{a,b}



Hospitalizations

- In the OP SUD cohort, 2 patients (9.5%) required at least 1 hospitalization while all 132 IP and 68 hybrid SUD patients, by definition, required at least 1 hospitalization.
 - Among the 2 patients with hospitalizations from the OP SUD cohort, a total of 2 hospital stays were reported, 1 of which was for the management of CRS.
 - Within the IP and hybrid SUD cohorts, a total of 163 and 141 hospitalizations were reported, respectively, of which all but 1 hospitalization in the hybrid SUD cohort were routine admissions.
- Median length of stay (LOS) per hospitalization was 2.0 days among OP SUD patients, 2.3 days among hybrid SUD patients, and 8.0 days among IP SUD patients (see **Figure 2**).
- In the OP SUD cohort, the number of days hospitalized per patient was 0.2 days vs 9.2 days per IP SUD patient, which is a 97.9% reduction in LOS for OP SUD patients (see **Figure 2**).

References

- FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761291s000lbl.pdf
- FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761342s000lbl.pdf
- Levy, Y., et al. (2024). *Blood* 144:7851.
- Rifkin, R., et al. (2024). *Blood* 144:4753.
- Sandahl, TB, et al. (2023). *Blood* 142:5154.
- Tan, CR., et al (2025). *Blood Cancer Journal* 15(1):53.

- Patients were followed up until the earliest of:
 - End of the SUD period, defined as 2 days after their last SUD;
 - Date of last patient encounter (with the site performing data abstraction);
 - Day before initiating next line of treatment; or
 - Date of death.
- Patients were categorized into OP (no planned hospitalizations during SUD phase), IP (≥1 planned hospitalization covering all SUD phase administrations), and hybrid (≥1 planned hospitalization but not covering all SUD administrations) SUD cohorts based on the intended SUD setting.

Statistical analysis

- Patient characteristics, safety outcomes, and hospitalizations were summarized descriptively for each of the OP, IP, and hybrid SUD cohorts.

Table 2. Safety outcomes^a

	OP SUD N = 21	IP SUD N = 132	Hybrid SUD N = 68
Patients with ICANS during the SUD period^a	0 (0.0%)	15 (11.4%)	5 (7.4%)
Patients with recurrent ICANS during the SUD period	0 (0.0%)	0 (0.0%)	1 (1.5%)
Tocilizumab use during the SUD period			
Overall	0 (0.0%)	65 (49.2%)	22 (32.4%)
Treatment or supportive care for CRS	0 (0.0%)	63 (47.7%)	21 (30.9%)
Prophylactic for CRS	0 (0.0%)	0 (0.0%)	1 (1.5%)
Treatments or supportive care for neurotoxicity events	0 (0.0%)	1 (0.8%)	0 (0.0%)
Prophylactic for neurotoxicity events	0 (0.0%)	1 (0.8%)	0 (0.0%)
G-CSF use during the SUD period			
Overall	0 (0.0%)	7 (5.3%)	1 (1.5%)
Prophylactic use	0 (0.0%)	6 (4.5%)	0 (0.0%)
Other use	0 (0.0%)	1 (0.8%)	1 (1.5%)
Steroid use during the SUD period			
Overall	14 (66.7%)	63 (47.7%)	50 (73.5%)
Pre-treatment per Tec/Tal label recommendation	10 (47.6%)	44 (33.3%)	46 (67.6%)
Treatment or supportive care for CRS	3 (14.3%)	21 (15.9%)	13 (19.1%)
Treatment or supportive care for neurotoxicity events	1 (4.8%)	10 (7.6%)	3 (4.4%)
Prophylactic for CRS	0 (0.0%)	3 (2.3%)	0 (0.0%)
Prophylactic for neurotoxicity events	0 (0.0%)	1 (0.8%)	0 (0.0%)

Abbreviations: CRS, cytokine release syndrome; G-CSF, granulocyte colony-stimulating factor; ICANS, immune effector cell-associated neurotoxicity syndrome; IP, inpatient; OP, outpatient; SUD, step-up dosing; Tal, Talquetamab; Tec, Teclistamab.

Notes:

a. The start date for the SUD period was defined as the index date (i.e., first dose of Tec or Tal SUD). The SUD period end date was defined as 2 days after the last SUD dose. For SUD period outcomes, patients were censored at the earliest of (i) the SUD period end date, (ii) date of last encounter with the site, (iii) the day before initiation of a subsequent line of therapy, or (iv) date of death. A single patient may experience multiple events within each reported safety outcome.

b. The grades of ICANS events were not collected.

Figure 2. Median total LOS (in days) and mean days of hospitalization per patient during the SUD period^a

