CO204

Outcomes of Outpatient Administration of Ciltacabtagene Autoleucel in Relapsed Refractory Multiple Myeloma

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OP administration and management of cilta-cel has been shown to produce clinical outcomes comparable to traditional IP administration while resulting in cost savings, upon instituting recommended processes

- OP administration of cilta-cel demonstrated comparable efficacy to IP administration while maintaining its safety profile
- OP administration is associated with less HCRU (i.e., fewer hospitalizations, shorter length of stay, fewer ICU admissions)
- Cost analyses revealed cost savings associated with OP administration
- There is limited literature on CAR-T OP administration. More research is needed to understand the outcomes and economic values of CAR-T OP administration, as well as the best practice of CAR-T OP administration

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De Braganca: Janssen: Current Employment; Johnson and Johnson: Current Employment, Current holder of stock options in a privately-held company. Alegria: Janssen: Current Employment. Perciavalle: Legend Biotech: Current Employment, Current equity holder in publicly-traded company. Ranjan: Putnam, Inizio Advisory: Current Employment, Other: Putnam Inizio Advisory was contracted by Janssen to work on this project. Potluri: Ranjan: Putnam, Inizio Advisory: Current Employment, Other: Putnam Inizio Advisory was contracted by Janssen to work on this project. Bixby: Janssen: Current Employment, Current equity holder in publicly-traded company. Qureshi: Janssen Scientific Affairs, LLC: Current Employment, Current equity holder in publicly-traded company

Introduction

- Ciltacabtagene autoleucel (cilta-cel) was approved in 2022 for adult patients with relapsed or refractory multiple myeloma (RRMM) after >=4 prior lines of therapy and in 2024 for those with ≥1 prior therapy[1]
- As with other CAR-T agents, cilta-cel is commonly administered in the inpatient (IP) setting with close monitoring for serious adverse events (AEs) like cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). There is however growing interest in outpatient (OP) use to lower costs and improve quality of life (QoL)[2,3]
- While real-world studies suggest feasibility of OP administration, data on comparative outcomes between the two settings is limited.[5-7] This systematic literature review (SLR) aimed to identify and evaluate efficacy, safety, healthcare resource utilization (HCRU) and cost outcomes of OP versus IP cilta-cel administration in patients with multiple myeloma

Methods

- This SLR was conducted in electronic databases (Medline, Embase, and Cochrane library) on October 01, 2024 to identify literature on OP and IP use of cilta-cel in RRMM patients
- This was supplemented by manual searches of conference proceedings, bibliography of published studies and grey literature
- No restrictions on study type or geography were applied
- The relevant outcomes considered were efficacy, safety, HCRU and costs (Table 1)
- A two-stage screening process was conducted followed by data extraction. Each stage involved two reviewers acting independently. Differences between two reviewers were resolved by a third reviewer
- A qualitative syntheses of data was carried out
- The SLR was conducted following best practice guidelines, including the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for systematic reviews[4]

Table 1. PICOS Criteria

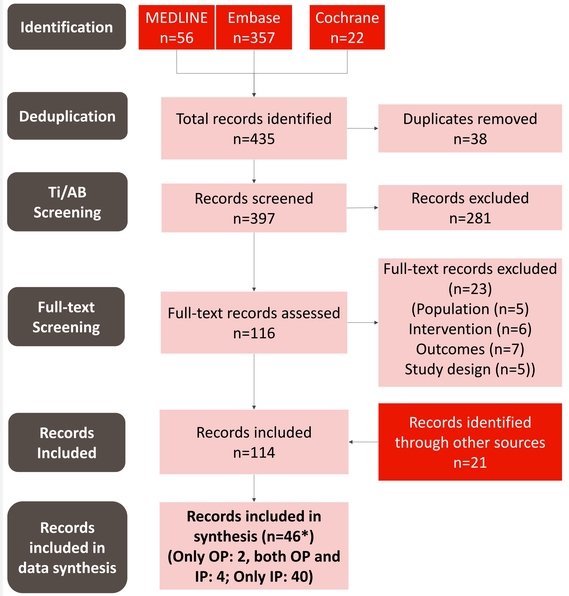
Parameter	Description
Population	Patients with multiple myeloma
Intervention/ Comparator	OP and/or IP use of cilta-cel
Outcomes	Overall response rate (ORR), progression-free survival (PFS), overall survival (OS), safety, cost, hospitalization rate, ICU admission rate
Study Design	Clinical trials, observational studies, economic evaluations, physician surveys

Results

Included studies

- 46 publications covering 5 clinical trials (9 sub-studies), 12 real-world studies, 6 economic evaluations, and 1 physician survey that reported outcomes for patients receiving cilta-cel in either OP or IP setting were identified (Figure 1)
- Clinical trials were conducted based almost entirely on IP administration; two trials reported one instance each of OP use but did not report outcomes separately for this setting.[8,9] One real-world study exclusively examined OP use,[5] while two covered use in both settings[6,7]
- Two economic evaluations reported outcomes for both settings
- Most studies were conducted in the US or were multinational

Figure 1. PRISMA Flowchart



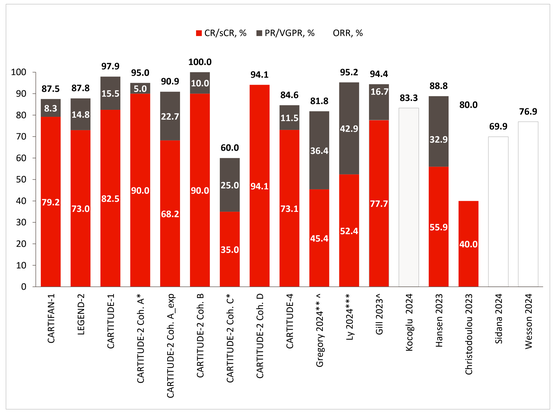
*Only records with unique and most recent data for various outcomes were considered for data synthesis

Ti/AB, Title/Abstract

Efficacy outcomes

- The outcomes reported of cilta-cel administration in OP and IP settings were comparable
  - The overall response rate was found to be 95% in one study conducted in the OP setting,[5] while it ranged from 60% to 100% in studies based in the IP setting
    - In the OP setting, Ly et al. reported complete response (CR) and partial response (PR) in 53% and 42% patients, respectively.[5]
    - Gregory et al., which included both OP and IP settings, showed an ORR of 82% (PR 36%).[7]
    - There was large variability in the CR reported in the IP setting (40%-94%) (Figure 2)
  - PFS and OS data for OP use of cilta-cel was sparse and not mature
    - PFS at one year was 86% in Waqar et al. for OP administration,[6] compared to 39-94% in the IP setting
    - OS at one year was 96% in Waqar et al. for OP administration,[6] compared to 78-94% in the IP setting

Figure 2. Response rates with cilta-cel in IP and OP settings



** One patient received cilta-cel in OP setting; ** Cumulative results for both IP and OP setting; *** Focused on OP patients; ^ CR includes VGPR*

Safety outcomes

- OP administration of cilta-cel was associated with a safety profile similar to IP administration
  - Any grade CRS was reported to be 79% in Ly et al. (median duration 2 days, median time to onset 6 days),[5] compared to 60%-100% in IP administration (median duration 2.5-9 days, median time to onset 7-9 days)
  - ICANS was reported to be 8% in Ly et al.,[5] compared to 1-36% in the IP setting
  - One study each from the OP (8.3%)[5] and IP (6.3%)[10] settings reported the incidence of hemophagocytic lymphohistiocytosis /immune effector cell-associated hemophagocytic syndrome with cilta-cel

Cost

- Two studies evaluated the economic impact of cilta-cel administration in the OP setting.
  - Jagannath et al. reported a cost savings of $18,922 per patient in the OP setting compared to use in the IP setting[11]
  - Hansen et al. reported a lower cost per complete responder and cost per month in PFS (by $7,598 and $294, respectively) for patients receiving cilta-cel in OP vs IP[12]
- In a mixed-methods qualitative study by Hansen et al., participants agreed that cilta-cel can be safely administered in an OP setting due to predictable, delayed onset of potential AEs offering financial sustainability, lower resource utilization, and greater patient autonomy[13]

HCRU

- Three studies reported HCRU data among patients who received CAR-T therapy in both OP and IP settings[7,10,11]
- OP administration of cilta-cel was associated with reduced post-infusion hospitalizations, ICU admissions and shorter length of stay (LoS)
  - Hospitalization was required in 86% and 93% in OP cohorts across two studies (mostly because of CRS and MM-related issues); 3% readmissions within 30 days in IP cohort[14]
  - Median LoS: 4-6.5 days (OP)[5,6]; 12-19 days (IP)[6,14,15]; 6 days (OP/IP)[7]
  - ICU admissions: 7% (OP)[5]; 20% (IP)[14]; 23% (OP/IP)[7]

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