Medicare and CAR T Therapy

February 11, 2019

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Agenda

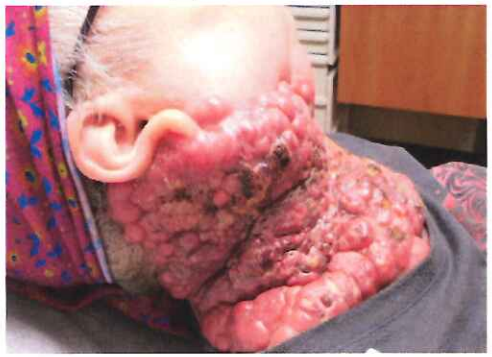
- Overview of YESCARTA®
  - Two Year Clinical Update
- CAR T Cell Therapy Reimbursement Policy
  - IPPS Recommendations
  - Novel Payment Arrangements

The Impact of YESCARTA

- Prior to Yescarta, relapse/refractory DLBCL patients had ~6.3 month survival
- At two years, with a one time infusion of Yescarta, half of this same patient population is still alive (overall survival has not yet been reached)

*Clinical trial data and RWD both show consistent safety and efficacy outcomes in Medicare aged patients compared to the overall eligible patient population

Day 0



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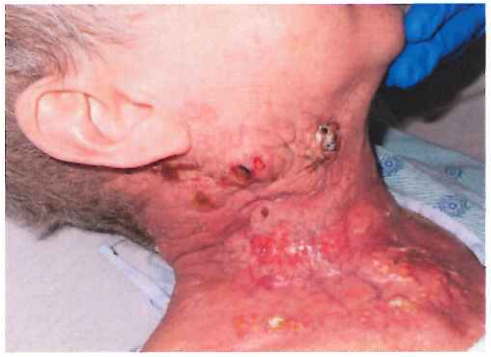

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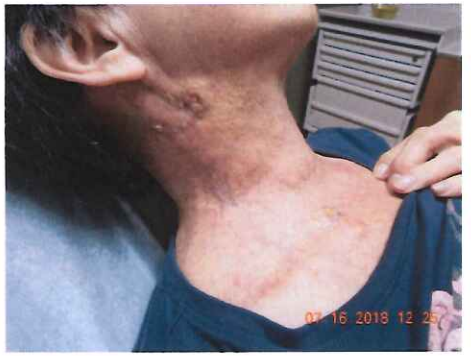

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Consistent Safety and Efficacy Outcomes in Medicare Aged (≥ 65 Year) Population Compared to Overall ZUMA-1 Population

	≥65 Yrs. (%) N=24	Overall (%) N=101
ORR	92	83
CRR	75	58
DRR	42	39
OS Rate	54	51

- Compared with subjects < 65 years of age, subjects ≥ 65 years of age had a lower incidence of SAEs (37% vs. 62%), a lower incidence of Grade 3 or higher infections (19% vs. 31%), and a higher incidence of Grade 3 or higher neurologic events (44% vs. 28%)
  - The higher incidence of neurologic events in subjects ≥ 65 years of age was driven by events that would be expected to occur more frequently in the ≥ 65 years age group (delirium, agitation, and disturbance in attention)
- Real world data on patients ≥ 65 years of age demonstrates comparable efficacy and safety to ZUMA-1

YESCARTA induces durable responses in many patients with large B-cell lymphoma who otherwise lack curative options. Clinical evidence supports the need for a reimbursement environment that is reflective of what a significant innovation CAR T cell therapies are.

ORR – Overall Response Rate; CRR – Complete Response Rate; DRR – Durable Response Rate; OS – Overall Survival; SAE – Serious Adverse Event
Source: Nastoupil LJ et al. ASH 2018. Abstract 91.

There Are Currently 74 YESCARTA® ATCs

Medicare Payment, Even With NTAP and Mark Up, Leaves Many Hospitals At A Loss and Reliant on Outlier Payment

	Charges as a Percentage of Cost			
	100%	**110%**	**300%**	**400%**
CAR T Charges	$373,000	$410, 300	$1.1M	$1.49M
MS-DRG 016 Payment	$39,950.76	$39,950.76	$39,950.76	$39,950.76
NTAP Payment	$40,900.00	$45,562.00	$134,150.00	$180,775.00
Outlier Payment	$12,104.49	$15,834.49	$86,704.49	$124,004.49
Total Payment (DRG+NTAP+Outlier)	$92,954.88	$101,347.38	$260,804.88	$344,729.88
Loss Based on Drug Costs	($280,045.12)	($271,652.62)	($112,195.12)	($28,270.12)

**Mean and median non-drug charges in Q1 – Q3 FY 2018 claims are $100K.*

FY 2018 claims data shows that most hospitals aren't marking up at 400%

Even with a markup, average losses are based on drug costs alone and do not account for non-drug treatment costs

A reliance on 400% markups and outlier payments to adequately pay hospitals is not sound policy.

- Small number of hospitals have markups that capture their CAR T costs appropriately, and one-third of hospitals that appear in clinical trial claims have not yet made a claim for non-clinical trial patients.
- Permanent reliance on outlier payments will cause outsize role of CAR Ts in outlier pool
- Existing work around strategies are insufficient to enable patient access

Analysis by The Moran Company, January 2019

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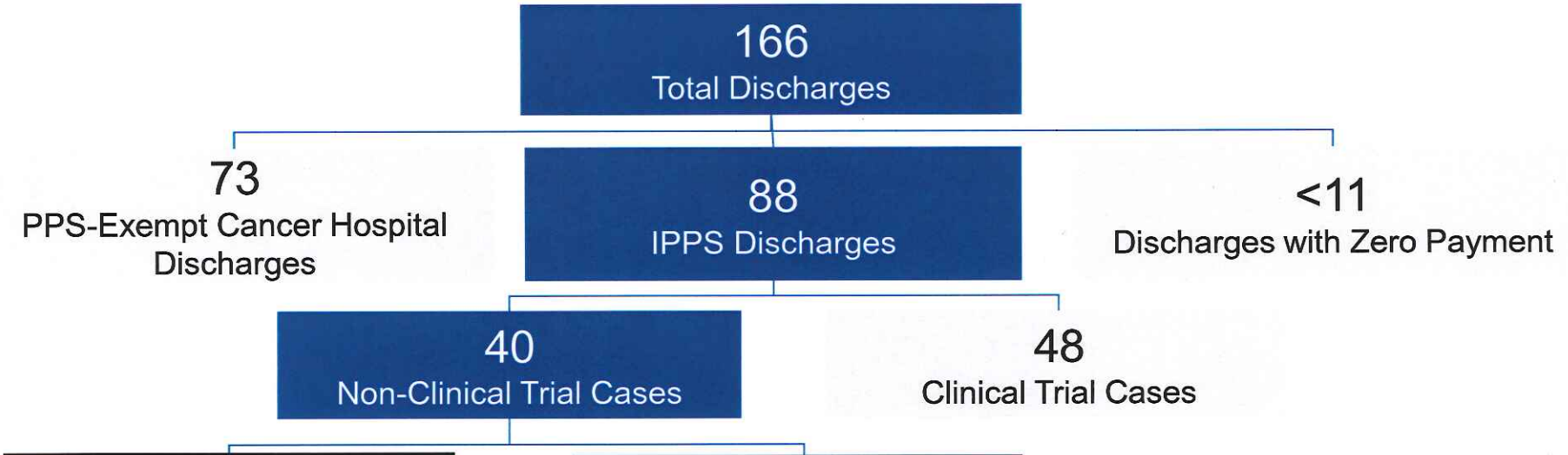
Before NTAP, More Than Half of All CAR T Discharges Were Not Made Whole for the Cost of Therapy

Medicare CAR T Claims from First Three Quarters of FY 2018



Payment	
Min.	~$10K
Max	~$480K
Median	~$360K
Mean	~$280K

Charges	
Min.	~$30K
Max	~$6.3M
Median	~$1.7M
Mean	~$1.5M

30 cases (75%) were outlier cases

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Medicare **Payment** Policy Recommendations

1 | **Change NTAP Payment Formula to Remove "Lesser Of" Language and Set Maximum NTAP Amount at 80%**

Current NTAP formula and "lesser of" language still leaves many hospitals with losses even with mark up on therapy.

2 | **Implement CCR 1.0 With Other Technical Changes to Ensure Payment Integrity**

Will address inconsistency across hospital charging practices and ensure that claims data provide accurate cost information for CAR T therapies in MS-DRG future rate setting.

3 | **New MS-DRG**

Outlier payments are designed for temporarily compensating hospitals for a portion of their losses on high cost cases until the payment system can adjust to capture the costs of these cases. We're concerned that without a separate MS-DRG for CAR T therapies, the current MS-DRG will not be able to adequately capture CAR T costs going forward, leaving hospitals with substantial losses on these cases into the future.

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Medicare Payment Policy Recommendations
1| Change NTAP Payment Formula

- Remove the "lesser of" language and set maximum NTAP at 80% of the invoice cost of therapy
- Mitigates reliance on outlier payment
- Table below models impact of policy change assuming hospitals are marking up the cost of therapy 110%; losses based upon drug costs, only

NTAP =	Lesser of 50% of Excess Costs or Invoice	50% of Invoice	75% of Invoice	80% of Invoice	90% of Invoice
MS-DRG 016 Payment	$39,950.76	$39,950.76	$39,950.76	$39,950.76	$39,950.76
NTAP Payment	$45,562	$186,500	$279,750	$298,400	$335,700
Outlier Payment	$15,834.49	$0.00	$0.00	$0.00	$0.00
Total Payment (DRG+NTAP+Outlier)	$101,347.38	$226,450.76	$319,700.76	$338,350.76	$375,650.76
Loss Based on Drug Costs	($271,652.62)	($146,549.24)	($53,299.24)	($34,649.24)	$2,650.76

**Mean and median non-drug charges in Q1 – Q3 FY 2018 claims are $100K.*

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Analysis by The Moran Company, January 2019

Medicare Payment Policy Recommendations
2| Implement CCR 1.0 With Technical Changes

- A CCR of 1.0, independent of changes to the NTAP formula, could help to address hospital payment concerns and enhance patient access
  - With appropriate controls to ensure that only invoice costs will go into NTAP, outlier and rate-setting calculations (e.g., new CAR T cost center and list drug HCPCS code on claim)
  - It may be worth exploring whether CMS has (or should be given) the discretion to exclude CAR T costs from wage index, IME, and DSH adjustments
- Table below models impact of CCR 1.0 policy change in addition to changes to NTAP formula (has same effect as all hospitals marking up 400%); losses based upon drug costs, only

NTAP =	Lesser of 50% of Excess Costs or Invoice	50% of Invoice	75% of Invoice	80% of Invoice	90% of Invoice
MS-DRG 016 Payment	$39,950.76	$39,950.76	$39,950.76	$39,950.76	$39,950.76
NTAP Payment	$180,775	$186,500	$279,750	$298,400	$335,700
Outlier Payment	$124,004.49	$119,424.19	$44,824.19	$29,904.19	$64.19
Total Payment (DRG+NTAP+Outlier)	$344,729.88	$345,874.95	$364,524.95	$368,254.95	$375,714.95
Loss Based on Drug Costs	($28,270.12)	($27,125.05)	($8,475.05)	($4,745.05)	$2,714.95

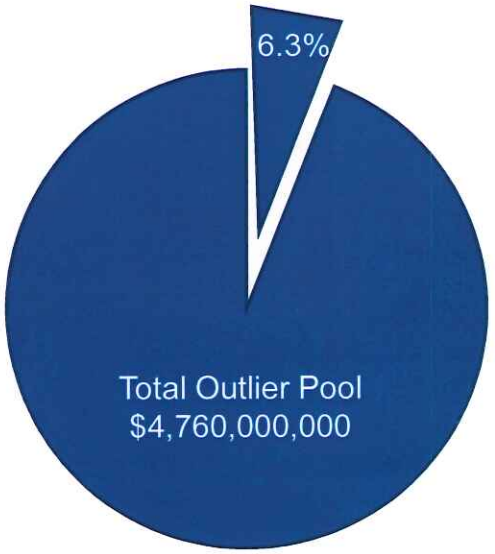
**Mean and median non-drug charges in Q1 – Q3 FY 2018 claims are $100K.*

Analysis by The Moran Company, January 2019.

Medicare Payment Policy Recommendations
3| New MS-DRG

- MS-DRG changes should be made before or immediately after NTAP expiration
- If MS-DRG changes aren't made after NTAP expiration, CAR T cases could easily account for more than 5% of all outlier cases
- Without a separate MS-DRG for CAR T therapies, the current MS-DRG will not be able to adequately capture CAR T costs going forward, leaving hospitals with unsustainable losses on these cases into the future
- If hospitals view losses on CAR T to be a permanent CMS policy, there is a risk that they will not undertake the investments necessary to provide these lifesaving therapies to patients

Illustration of Burden on IPPS Outlier Pool	
Avg. Outlier Pmt. CAR T Cases	$300K
CAR T Cases	1,000
Outlier Pmts. For CAR T Cases	$300M



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Analysis of Q1 – Q3 FY 2018 SAF by The Moran Company, January 2019

Novel Payment for CAR T Cell Therapy: Goals

1 | **Eliminate Site of Service Financial Disparity By Creating Site Neutral Payment**
We are concerned that absent significant changes to how CAR T therapies are paid for in the inpatient setting, providers may be driven by financial incentives rather than the site of service or therapy that is most clinically appropriate for patients.

2 | **Pay for Value**
CAR T therapies are a significant clinical improvement over standard of care treatment for lymphoma patients. YESCARTA clinical evidence supports the need for a reimbursement environment that is reflective of what a significant innovation CAR T cell therapies are.

3 | **Ensure Patient Access**
We are focused on reducing barriers for patient access and support redesigning benefits for durable and potentially curative therapies

Novel Payment for CAR T Cell Therapy: Approaches

- **Outcomes Based Payment Model Under CMMI**
  - Payment benchmarked to outcomes
  - Leverage NCD process to establish a mechanism for tracking outcomes and adjudicating outcomes-based payment
  - Contracting directly between CMMI (fiscal intermediary/contractor) and Kite/Gilead/all cell therapy manufacturers (less complex); OR
  - Contracting between CMMI – FACT accredited treatment centers – and Kite/Gilead/all cell therapy manufacturers (more complex)

- **New Technology Outcomes Payment**
  - Similar to outcomes-based model but payment is added to traditional NTAP

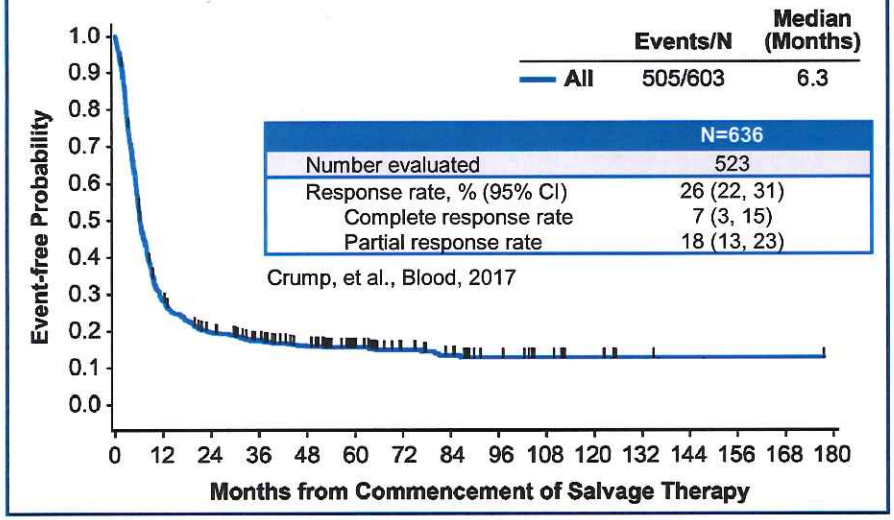
Appendix

YESCARTA Clinical Update

To date, YESCARTA has shown compelling outcomes in this hard to treat patient population

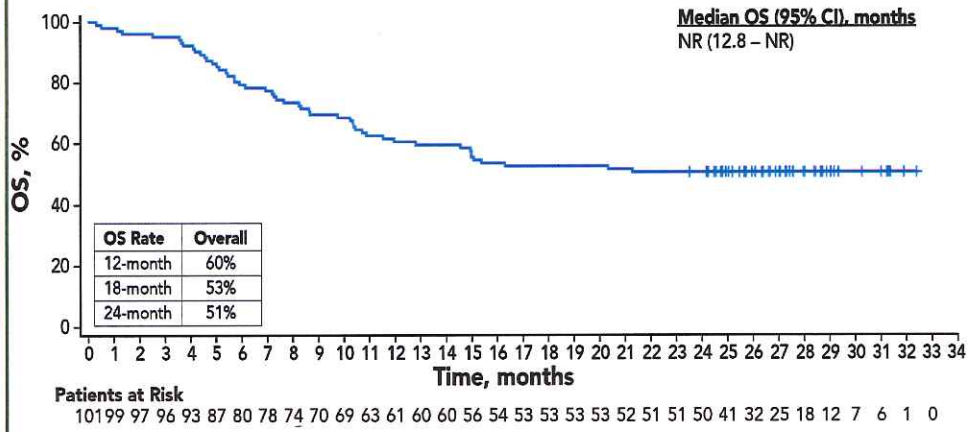
SCHOLAR-1: Median OS of 6.3 Months

SCHOLAR-1: Unmet Medical Need in Patients with Refractory Large B-cell Lymphoma



Crump, et al., Blood, 2017

YESCARTA: Median OS Not Yet Reached at 27.1 Months

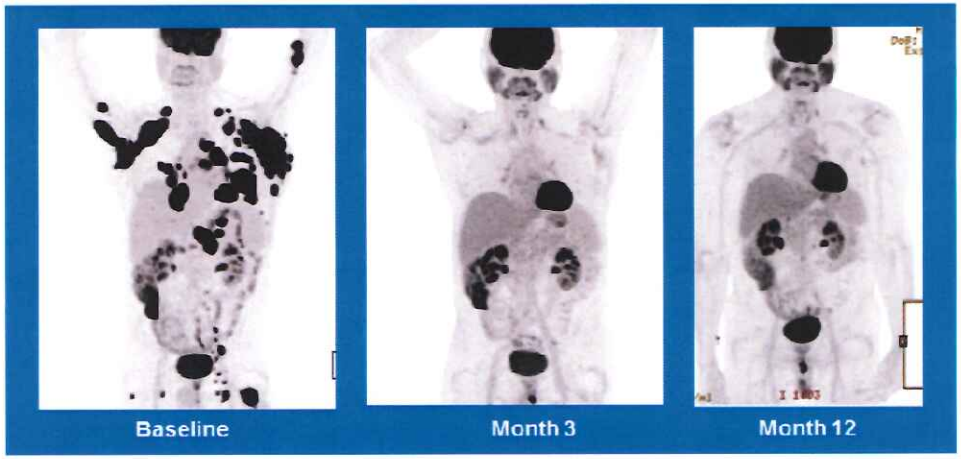


For FDA approval, efficacy was established on the basis of complete remission and duration of response. OS was a secondary endpoint of the YESCARTA pivotal study.

OS – Overall Survival

Crump et al, Blood 2017 (SCHOLAR-1); Locke et al., Lancet Oncology 2018

The Impact of YESCARTA



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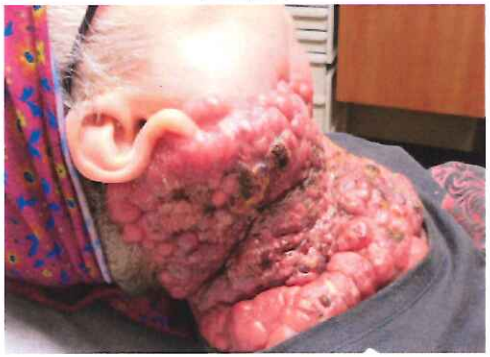

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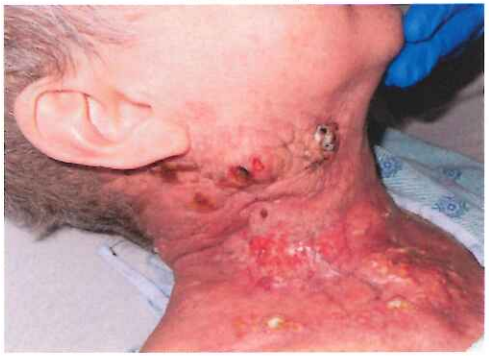

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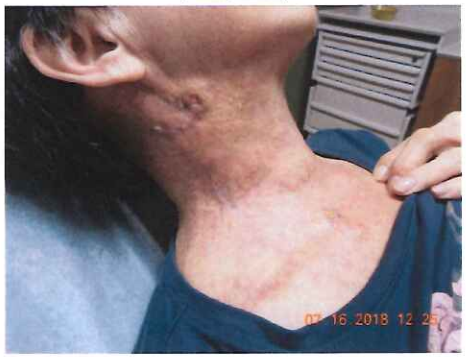

BARBARA ANN Karmanos CANCER INSTITUTE Wayne State University

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