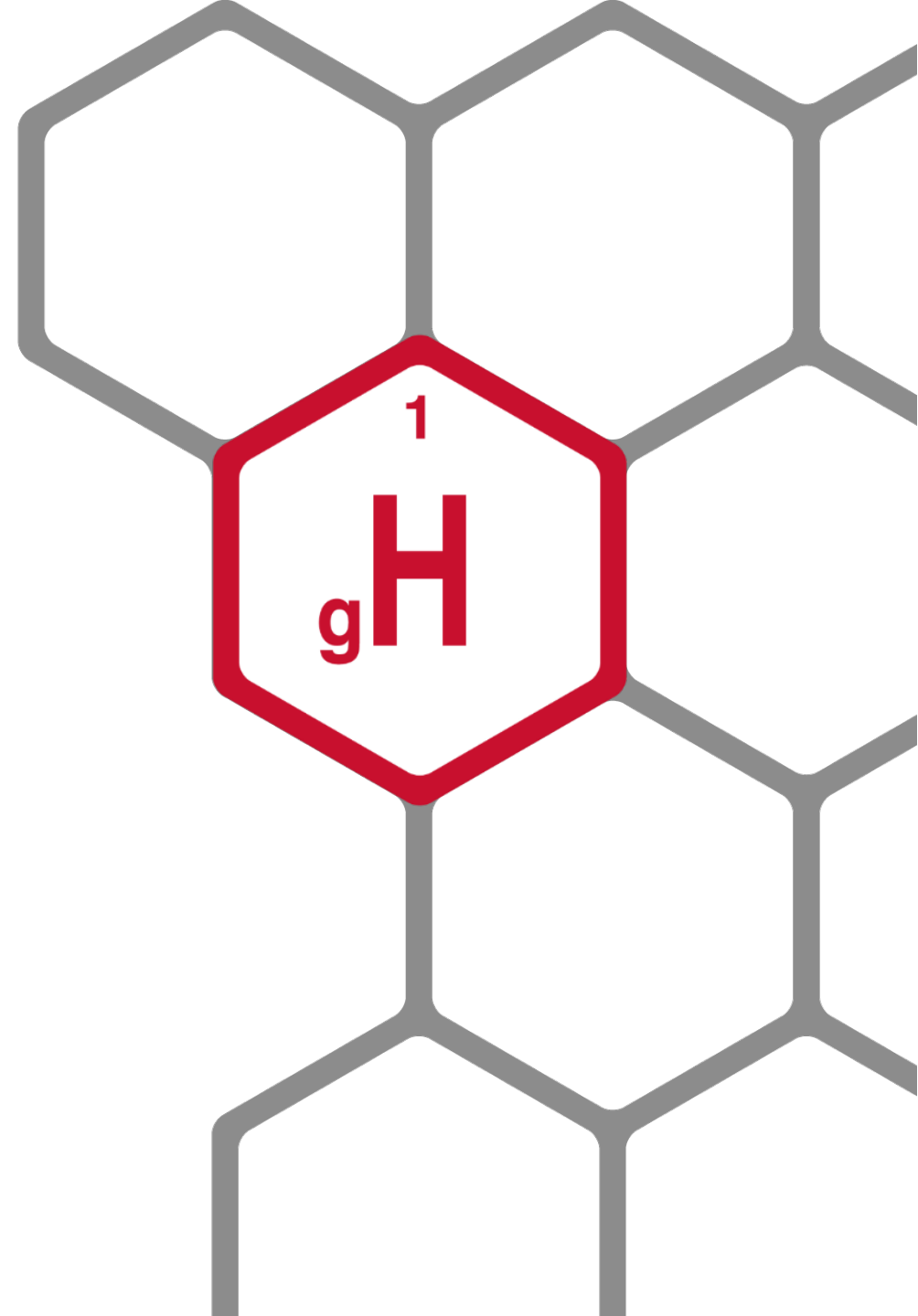


# CAR-T Reimbursement in the US

## August 2019 Update

groupH Analysis

August 27<sup>th</sup>, 2019



# Our previous analysis of CAR-T reimbursement in the US described how inadequate Medicare coverage for inpatients was disincentivizing use by hospitals / providers



May 2019

## Summary: current reimbursement

### Current reimbursement differs significantly by payer type

- **Commercial:** good coverage with few restrictions beyond the product label → net positive financial outcome for hospitals providing CAR-T therapy
- **Medicare:** coverage differs significantly by setting:
  - Outpatient: ASP +6%
  - Inpatient: CMS update for PPS inpatient for 2019 allows an MS-DRG 16 payment, plus NTAP, and possible Outlier Payment
    - However, hospitals need to mark-up the CAR-T price significantly in order to achieve the max NTAP payment, but many hospitals may not know to do this
    - This is a significant improvement for providers over 2018 coverage, but still leaves hospitals with a significant shortfall on the product acquisition cost
- **Medicaid:** until NCA, coverage differs by state

### Risk-sharing

- Novartis's risk-sharing approach for Kymriah in ALL is at an early stage – it is being slowly rolled out with providers and has been adopted by MassHealth Medicaid

### As a result...

- Inadequate reimbursement coverage for Medicare beneficiaries means that leading hospitals with financial resources are subsidizing treatments, while others are forced to be selective in which patients they treat

### Conclusion

- Reimbursement reform is imperative if CAR-T therapy is going to be is going to live up to its exciting promise

### CMS Feb 15<sup>th</sup> 2019 update

- Medicare will provide CAR-T coverage with evidence development (CED); reimbursement levels not improved
- The CED could prove to be too burdensome for some providers
- The CED gives providers a legal route to opt-out of providing CAR-Ts to Medicare patients

Source: groupH research and analysis

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# On August 7th, CMS published a memo providing an update to CAR-T reimbursement; news headlines imply that CAR-Ts is now fully covered and reimbursed



*“In the absence of a national coverage decision, basically, hospitals and providers are going to our Medicare contractors, or MACs, and are making these decisions. There’s a lot of confusions about ‘Is this covered? How is it covered?’.*

*Today’s decision makes it very clear that ‘Yes, this is covered.’*  
*We’re paying that not only for CAR-T, but all the related services.* *The administration of the drug. The collection of the cells. The manipulation of the cells and then putting it back into the patient. And then any of their outpatient or inpatient care as well.”*

**– Seema Verma, CMS Administrator (Aug 2019)**



**groupH analysis finds that while coverage clarity has improved, overall reimbursement will continue to be poor and limit CAR-T uptake**

# The details: the August CMS update (1) increases NTAP payments, (2) loosens coverage requirements, and (3) adds potential for future off-label use



## CMS August 2019 Update

### Increased NTAP Payments

#### *NTAP increased to 65%*

**What's changed?** In 2018, NTAP was capped at 50% of the new technology cost. This is now increased to 65% to the end of 2020.

**Stakeholder Reaction:** Mixed overall. ASH President Dr. Roy Silverstein not satisfied since CCR of 1.0 was not included and reimbursement not at 80% leaving significant reimbursement GAPs. groupH analysis confirms this assessment (see slide 7).



**Implication:** Although it appears that CMS is improving the situation, the reality is that reimbursement will remain inadequate. Furthermore, our analysis shows that outlier payment decreases as NTAP payment increases.

### Loosened Coverage Requirements

#### *No CED, Only REMS*

**What's changed?** In the February 2019 CMS memo, CMS reimbursement would only be provided to institutions who participated in a Coverage with Evidence (CED) program, adding burden especially for lower volume centers that many considered not treating Medicare patients. Now that the requirement is lifted, providers only need to comply with the manufacturer REMS requirement. CMS will rely on the REMS data to assess long term outcomes.

**Stakeholder Reaction:** ASH praised the elimination of CED requirement.



**Implication:** No CED widens the potential pool of CAR-T providers

### Potential Future Off-label Use

#### *Compendia listing for off-label*

**What's changed?** Previously, CMS covered only “relapsed or refractory cancer”. CMS coverage now includes (1) FDA label and (2) off-label use for approved products if they receive listing in FDA approved compendia (such as NCCN guidelines). CMS will not reimburse non-approved products (such as pipeline agents).

**Stakeholder Reaction:** ASH is pleased with the expanded coverage.



**Questions:** Will commercial payers follow suit on off-label use? For manufactures, does the off-label compendia change the development strategy to “fast-to-market” and gaming compendia requirements for off-label use in development indications?

# Despite news headlines implying full reimbursement, key stakeholders have expressed the view that the increased NTAP payment is still inadequate



## Stakeholder Reactions to CMS NTAP Increase



*"Previous reimbursement was woefully inadequate and this increase to 65% still leaves a significant gap. However the modest increase potentially increases access for patients to this therapy"*

**– Joseph McGuirk, director of Hem/Onc at KU Cancer Center.**

*"While this is a step in the right direction, it represents a piecemeal approach to a systemic problem and one that leaves hospitals with unsustainable expenses."*

**– Dr. Roy Silverstein, President of ASH**



*"We are concerned reimbursement doesn't go far enough, as it still leaves providers with a potential six-figure deficits. A reimbursement gap of that size is unsustainable and will lead to patient access issues. Additionally, we continue to be concerned that CMS has not addressed the need for adequate CAR-T reimbursement for PPS exempt cancer hospitals"*

**– Dr. Wui-Jin Koh, CMO of NCCN**



*"Unfortunately, a broad coverage policy paired with poor reimbursement leaves institutions in the difficult position of being required to cover this therapy while continuing to receive inadequate payment to cover the costs associated with it."*

**– ASH policy Statement August 14<sup>th</sup>, 2019**

# In May 2019, our review of ASBMT analysis illustrated that hospitals need to mark-up CAR-T price significantly in order to achieve the max NTAP payment



## Illustrative Example of 2 Hospitals – 110% vs. 400% CAR-T Mark-Up

	Hospital A 110% CAR-T Mark-Up	Hospital B 400% CAR-T Mark-Up
Assumptions	<b>Wage Index: 1.0, Hospital CCR: 0.25, CAR-T Drug Cost: \$373,000</b> <b>MS DRG 016 Base Payment w/ no Hospital adjustment: \$39,951, Fixed Loss Outlier Amount: \$25,769</b>	
Hospital Charges	<ul style="list-style-type: none"> <li>CAR-T Cost w/ Mark-Up: \$413,300</li> <li>Non-Drug Inpatient Charges: \$228,000</li> <li>Total Charges: \$638,300</li> <li>Hospital Cost (Charges x CCR): \$159,575 <ul style="list-style-type: none"> <li>Non-Drug Cost: \$57,000</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>CAR-T Cost w/ Mark-Up: \$1,492,000</li> <li>Non-Drug Inpatient Charges: \$228,000</li> <li>Total Charges: \$1,720,000</li> <li>Hospital Cost (Charges x CCR): \$430,000 <ul style="list-style-type: none"> <li>Non-Drug Cost: \$57,000</li> </ul> </li> </ul>
50% NTAP Payment	<ul style="list-style-type: none"> <li>Hospital Cost: \$159,575</li> <li>Excess Cost (Hosp. Cost – DRG): \$119,624</li> <li>50% of Excess Cost: \$59,812</li> <li>NTAP CAP (50% of CAR-T): \$186,500</li> <li>Estimated NTAP (Lower of NTAP vs 50% Excess cost): <b>\$59,812</b></li> </ul>	<ul style="list-style-type: none"> <li>Hospital Cost: \$430,000</li> <li>Excess Cost (Hosp. Cost – DRG): \$390,049</li> <li>50% of Excess Cost: \$195,025</li> <li>NTAP CAP (50% of CAR-T): \$186,500</li> <li>Estimated NTAP (Lower of NTAP vs 50% Excess cost): <b>\$186,500</b></li> </ul>
Outlier Payment	<ul style="list-style-type: none"> <li>Hospital Cost: \$159,575</li> <li>Outlier Threshold (MS-DRG PMT + NTAP + Fixed Loss Amount): \$125,532</li> <li>Outlier Payment Step 1 (Hospital Cost – Outlier Threshold): \$34,043</li> <li>Final Outlier Payment (80% of Step 1): <b>\$27,234</b></li> </ul>	<ul style="list-style-type: none"> <li>Hospital Cost: \$430,000</li> <li>Outlier Threshold (MS-DRG PMT + NTAP + Fixed Loss Amount): \$252,220</li> <li>Outlier Payment Step 1 (Hospital Cost – Outlier Threshold): \$177,780</li> <li>Final Outlier Payment (80% of Step 1): <b>\$142,224</b></li> </ul>
Total Payments	<b>\$126,997</b> (MS-DRG 016 + NTAP + Outlier Payment)	<b>\$368,675</b> (MS-DRG 016 + NTAP + Outlier Payment)
Profit /Loss	<b>\$303,003 Loss</b> (Drug Cost + Non-Drug Cost – Total Reimbursement)	<b>\$61,325 Loss</b> (Drug Cost + Non-Drug Cost – Total Reimbursement)

May 2019



**Further analysis shows that even if CMS adopted ASH recommended 80% NTAP payment levels, overall reimbursement to providers would still be inadequate without other changes to the overall reimbursement calculation**

### Example of 2 Hospitals – 110% vs. 400% CAR-T Mark-Up across NTAP payments

	Hospital A 110% CAR-T Mark-Up			Hospital B 400% CAR-T Mark-Up		
NTAP %	50%	65%	80%	50%	65%	80%
MS-DRG	~\$40k					
NTAP Payment	\$59.8k	\$77.7k	\$95.7k	\$186.5k	\$242.5k	\$298.4k
Outlier Payment	\$27.2k	\$12.9k	\$0	\$142.2k	\$97.5k	\$52.7k
Total Payments	\$127k	\$130.6k	\$135.7	\$368.7	\$379.9k	\$391.1k
% Difference	N/A	+2.8%	+6.8%	N/A	+3.0%	+6.1%

- Overall reimbursement increase is modest since increased NTAP payments are offsets by lessened outlier payments
- CMS failure to adopt ASH request of a CCR of 1.0 means that hospitals will still need significant markups to maximize reimbursement payments



# CMS reimbursement for CAR-T may change after EOY 2020 but no timeline for expected changes is publically available

## Increase NTAP ends after 2020

- Current 65% NTAP increase ends end of year 2020
- CMS has not mentioned a renewal timeline for current NTAP policy

## Outcome data from REMS

- CMS will rely on patient data collected by the FDA through existing REMS programs for current CAR-Ts and the NCI for future policy

## How will CMS address CAR-T Reimbursement after 2020?

- Will CMS have enough data within another year to create a specific MS-DRG specifically for CAR-Ts?
- If there is not enough data yet for a CAR-T MS-DRG, how will current coverage and reimbursement change?
  - Heed to NCCN and ASH recommendations of 80% NTAP, CCR of 1.0?



# Conclusion – despite improvements in coverage and lower administrative burden, lack of reimbursement is the bottleneck to greater CAR-T uptake



## Lack of Reimbursement

- Overall reimbursement increase from NTAP increase is minimal due to offsetting by lower outlier payments
- Only the financially stronger institutions will be able to provide CAR-T therapy to Medicare patients

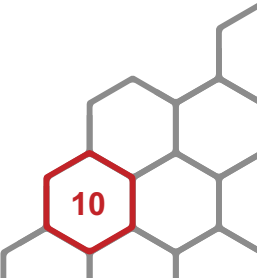
## Coverage & Limited Requirements

- Many positive factors that can help drive uptake once reimbursement is sorted:
  - No burdensome CED
  - Limited REMs requirements
  - Liberal off label coverage requirements



# Appendix

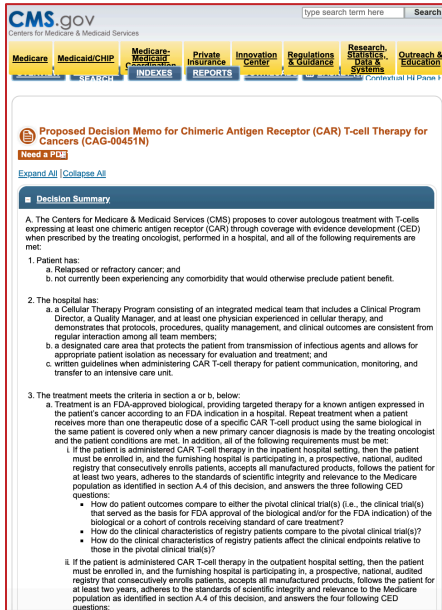
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# CMS CAR-T Memo: removal of CED requirement previously introduced (CMS CAR-T Memo, Feb 2019)



## Excerpts from the CMS CAR-T Memo (Aug 7<sup>th</sup>, 2019)



**Comment #1:** We received many comments ranging from support for CED to others who believe that CED is not warranted for CAR T-cell therapy.

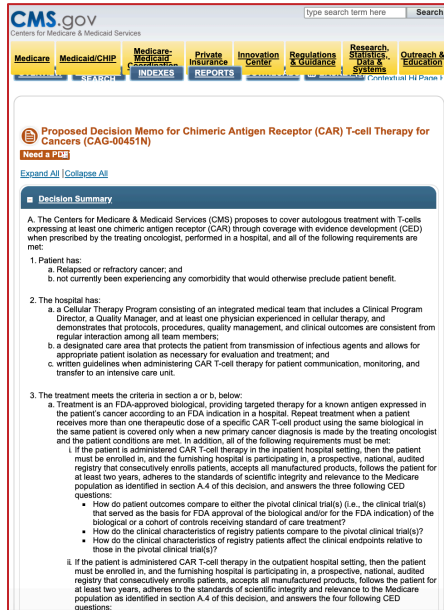
**Response #1:** We have removed the CED requirement in this final decision in order to provide Medicare coverage of CAR-T consistent with the language in section 1861(t)(2). We also recognize that there is important ongoing research by scientists and manufacturers and note that the routine costs of clinical trials where CAR T-cell therapy is an investigational agent would be covered per our existing Clinical Trial Policy [NCD 310.1]. We also note that FDA has required post-marketing studies... CAR T-cell therapy has been shown to induce remission in carefully identified relapsed or refractory cancer patients in appropriate settings of care. Informed decision making between a physician and patient remains key to determining the best treatment.

**Removal of the CED allows smaller oncology healthcare facilities to treat CAR-T patients without excess administrative burden**

# CMS CAR-T Memo: CMS is not restricting CAR-T administration sites if the facility meets the CAR-T REMs requirements



## Excerpts from the CMS CAR-T Memo (Aug 7<sup>th</sup>, 2019)



**Comment #1:** FDA approved CAR T-cell products qualify as a "medical and other health service" as a biological administered incident to a physician's service in the hospital outpatient department. A few commenters requested coverage consistent with FDA approval and labeling consistent with section 1861(t) of the Act.

**Response #1:** In this final decision, we indicate that CAR T-cell therapy also falls under the category of drugs and biologicals at section 1861(t) of the Act. We are maintaining the references to 1861(b) and 1861(s)(2)(B) to reflect the fact that per FDA requirements, the approved CAR T therapies are only available through healthcare facilities that are enrolled in the REMS requirements. We note that the list of benefit categories may not be an exhaustive list of all applicable Medicare benefit categories for the item or service.

**Comment #2:** Commenters shared their support for the proposal to cover CAR T-cell therapy administered in the hospital. One commenter stated that hospitals as noted by the Foundation for the Accreditation of Cellular Therapy (FACT) are the providers currently equipped to ensure the safest and most efficacious delivery of CAR T-cell therapy.

**Response #2:** CMS is finalizing this NCD to provide for uniform national coverage consistent with section 1861(t) of the Act. Therefore, we are not requiring accreditation by FACT as a condition of coverage in our final decision. Per the FDA, hospitals and their associated clinics may administer CAR T if the facilities are enrolled in with the REMS requirements

**Less restrictions on sites of care will allow CAR-T therapies a better chance of becoming a more mainstream therapy as experience accumulates**

# REMs requirement for CAR-T isn't overly burdensome & centers around management of CRS & neurotoxicity



## Pillars of CAR-T REMs Program

### Availability of Tocilizumab

- Ensuring that hospitals and their associated clinics that dispense therapy are specially certified and have on-site, immediate access to tocilizumab

### HCP Training on CRS & Neurotoxicity

- Ensuring those who prescribe, dispense, or administer therapy are aware of how to manage the risks of cytokine release syndrome and neurological toxicities.

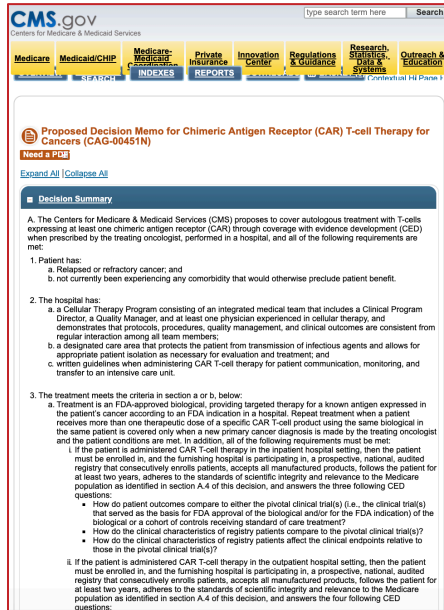
### Observation Studies for long-term outcomes

- FDA 15-year post marketing observational studies to assess long-term safety by following at least 1500 patients for 15 years after product administration

# CMS CAR-T Memo: Only one recommendation from a CMS approved compendia is needed for off-label use of an FDA approved CAR-T



## Excerpts from the CMS CAR-T Memo (Aug 7<sup>th</sup>, 2019)



- **Off-label use is allowed as long as the product is already FDA approved in another indication –** *“medically accepted indication - i.e., uses approved by the FDA, and other uses provided that the product is FDA-approved and the use is supported by one or more citations in certain compendia, unless the Secretary determines that such off-label use is not appropriate.”*
- **Off-label use of a non-FDA approved drug (still in development) is not covered –** *“The use of non-FDA-approved autologous T-cells expressing at least one CAR is non-covered.”*
- **Off-label use only requires a listing in a CMS approved compendia meaning that NCCN recommendation for off label is not necessary –** *“Additional uses of an FDA-approved CAR T-cell product are coverable when recommended for use by a citation in one or more CMS-approved compendia. As a result, coverage will be provided consistently on a national level and contractors local policies cannot supersede the NCD. In this final decision, off-label coverage will not be limited to uses recommended by NCCN.”*

**Will this liberal off label requirement incentive manufacturers to consider a fast-to-market strategy and a different life cycle management approach?  
Will commercial payers adopt off-label use to the same extent as CMS?**

## groupH, San Francisco

### Morris Paterson

morris.paterson@groupH.com  
m +1 415 969 1986

### Michael Hy

michael.hy@groupH.com



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