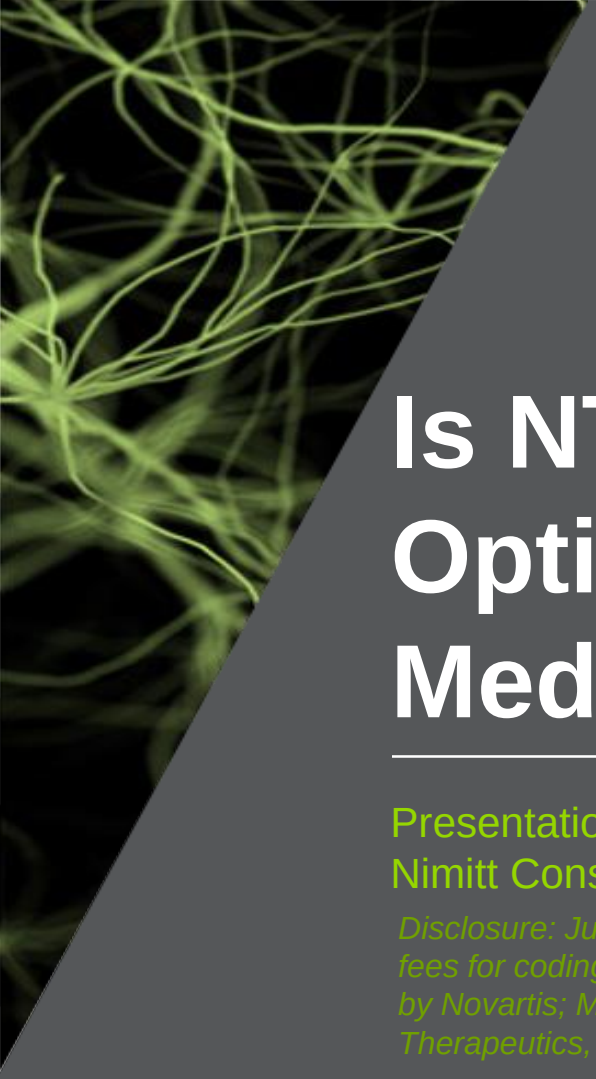


Is NTAP Tapped Out? Options for Future Medicare CAR-T Payment

Presentation by Jugna Shah, MPH, CHRI
Nimitt Consulting, Inc.

Disclosure: Jugna Shah has received consulting fees for coding and reimbursement education, by Novartis; Miltenyi Biotec, Autolus Therapeutics, and AlloVir

November 2019

Overview

- A Look at CMS' Concerns: the Money, the Rules, and Usual Approaches
- Getting from Here to Where: Taking a Ride on the Payment Policy Train
  - Stop 1: FY 2020
  - Stop 2: FY 2021… Life After the NTAP?
  - Stop 3: Assessing the Gaps
  - Stop 4: Crossing the Chasm
  - Stop 5: Laying New Track

The View From CMS' Seat: Bracing for the Tsunami

By 2027, nearly half of U.S. health spending, or 47%, will be financed by federal, state and local governments as baby boomers age into Medicare, which will remain a key driver of overall healthcare outlays. In 2017, federal, state and local governments financed 45% of national health spending.

" Medicare spending growth is projected to average 7.4% over 2018-2017, the fastest rate among the major payers ," the CMS report said.

2,076 views | Feb 20, 2019, 04:00pm

Baby Boomers To Push U.S. Health Spending To $6 Trillion By 2027

Bruce Japsen Senior Contributor
Healthcare
I write about healthcare business and policy

Forbes, Feb. 2019

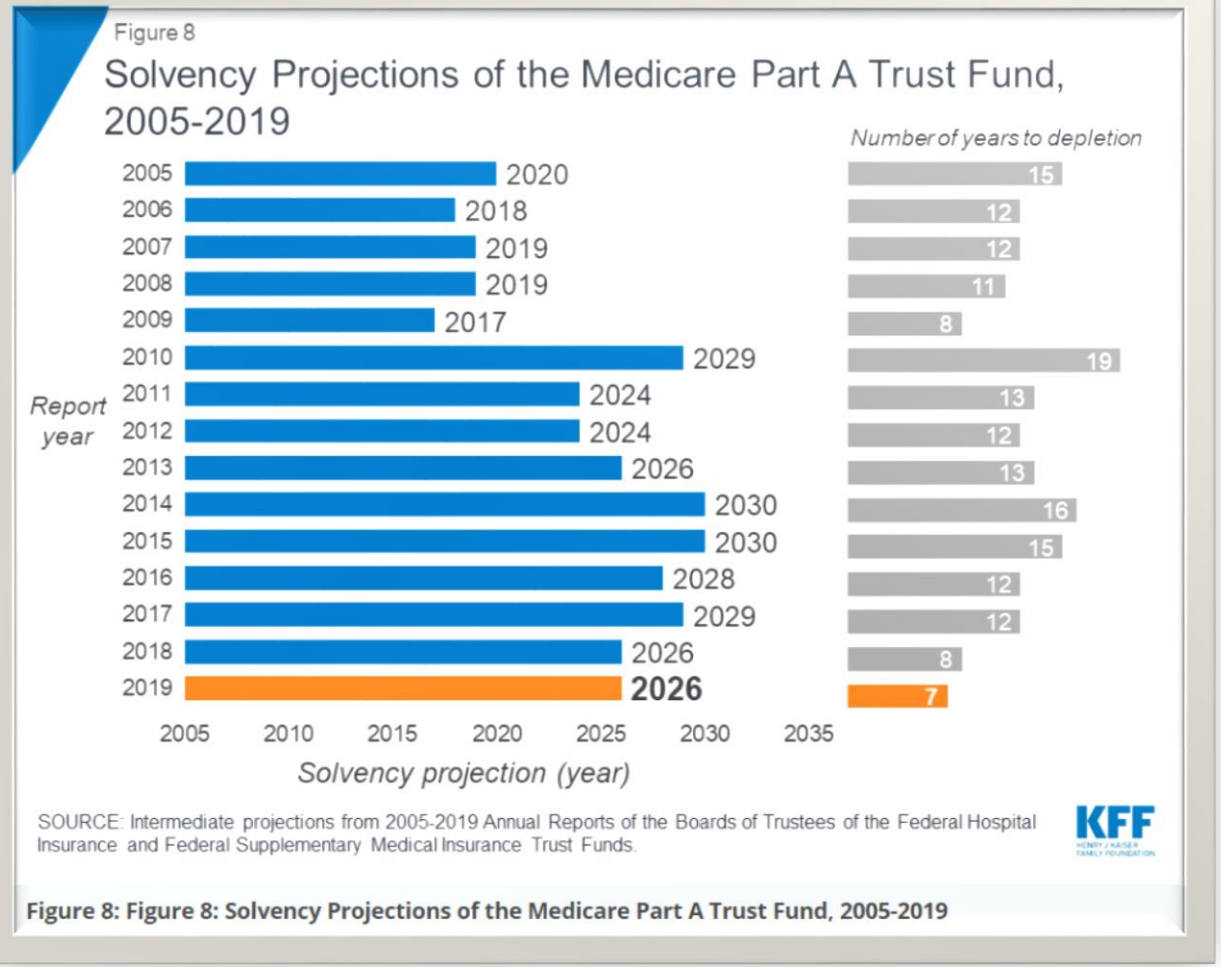
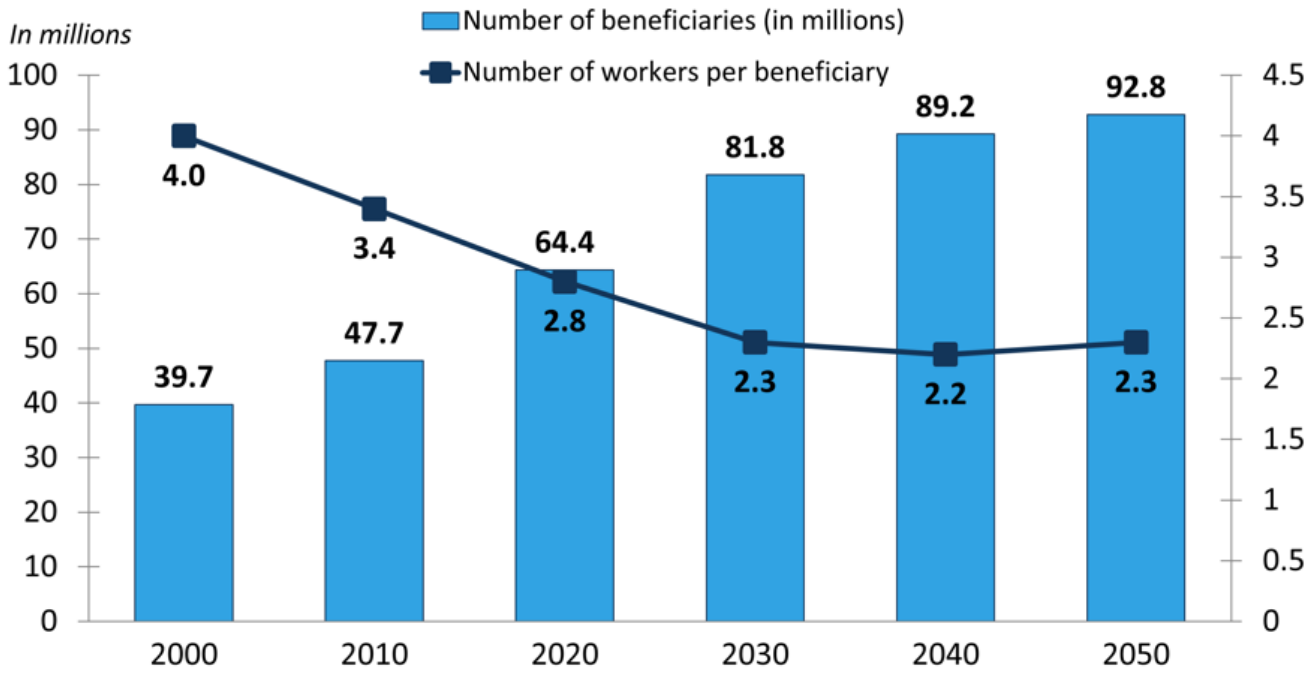


Figure 8: Figure 8: Solvency Projections of the Medicare Part A Trust Fund, 2005-2019

The View From CMS' Seat: Bracing for the Tsunami (Cont.)

Figure 31

Number of Medicare Beneficiaries and Number of Workers Per Beneficiary, 2000-2050



SOURCE: Kaiser Family Foundation based on the 2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.

Trust Fund Trend: More Beneficiaries, Less Money…At the Same Time The Tsunami is Coming

Some CY 2019 CAR-T Statements from CMS

POLITICS

STAT+

As CAR-T changes lives, Medicare's top official explains why it's proving so hard to pay for it

By NICHOLAS FLORKO @NicholasFlorko / AUGUST 6, 2019

"I'm equally frustrated about the challenges that we've had with figuring out how to pay for CAR-T," Verma said. "CAR-T came out and it was available in the fall of 2017, and here we are — almost two years later and we're struggling to figure out what the reimbursement should be."

Verma insists her agency is hamstrung by existing laws that required a certain level of data before CMS can set reimbursement rules specific to CAR-T. That data doesn't currently exist, she said, partially because the therapies are so new. She also insists some hospitals the existing system work — negotiating hard and cobbling together payments fro make sure they're not losing money.

ening the Medicare program by new and potentially lifesaving gene therapy, CAR T-cell therapies is promising new area of medicine nts who had nowhere else to turn. today's coverage decision provides consistent and predictable patient access nationwide. CMS will work closely with our sister agencies to monitor outcomes

How do you think we get to a point where hospitals are whole here?

The idea here is that it would encourage negotiation between the hospital and the manufacturer. … If we just set it to whatever they ask for, then we're not going to have that level of negotiation.

So if you set the NTAP at 100%, as hospitals suggested, that would essentially tell the hospitals you don't need to negotiate to get this price down, we will just pay you the whole amount?

That's right. It's a great microcosm into the complexities of government price setting.

CMS is “Hamstrung” Because It’s Reluctant To Veer off the Usual Path When it Comes to Setting Payment Policy

Typical CMS’ Constraints

- Part A Trust Fund
- Pipeline awareness
- Questions about care setting
- Statutory authority
- Regulatory processes and timelines
- Existing payment system built on averages
- Opening the floodgates for more “unique/one-off requests
- Limited data at time of approval and even now from treatment centers
- Political environment

Cards CMS Has Played

- Granted NTAP to CAR-T
- Increased NTAP cap from 50 to 65% for all designated NTAPs
- Finalized a National Coverage Decision (NCD) for CAR-T with few requirements
- Outpatient product payment based on average sales price plus 6%
- Considering new MS-DRG for 2021
- Significant staff time and resources spent on CAR-T discussions

Stop #1 FY 2020: Major Delays in Need of Policy Changes, or Not?

Whether the payment train is on schedule, delayed, or broke down depends…

The CMS conductor says…	*The provider passengers say…*
Payment Train is On Time	**Payment Train is Delayed**
• CMS increased the NTAP cap (for all NTAP products) from 50 to 65%	• CMS has not even begun to model new payment methods which are very

Bottom Line: CMS has kicked the can down the road by refusing to make any structural changes to its inpatient payment system for FY 2020, so what does this mean for the next set of products as well as for FY 2021 when NTAP expires?

Stop #2: End of the Line for CAR-T NTAP in FY 2021?

- NTAP to expire – September 30, 2020
- Will CMS extend NTAP for another year? If not, what might we see in terms of:
  - Payment policies
  - Provider reimbursement
  - Impact on patient access
  - Impact on future products
- What do we know about CMS' thinking for FY 2021?

What CMS Requested Comments on for FY 2021:

The most appropriate way to develop the relative weight for a new MS–DRG

How to address the significant number of cases involving clinical trials

Other approaches for setting the relative weight if we were to finalize a new MS–DRG

Whether we should not geographically adjust the payment for any new MS–DRG or apply adjustments to a lower proportion of payments

Whether IME and DSH payments should not be made or whether a reduced applicable percentages should be used

Use of exceptions and adjustments authority

Payment alternatives and how these payment alternatives would affect access to care, and affect incentives to encourage lower drug prices

What Commenters Told CMS:

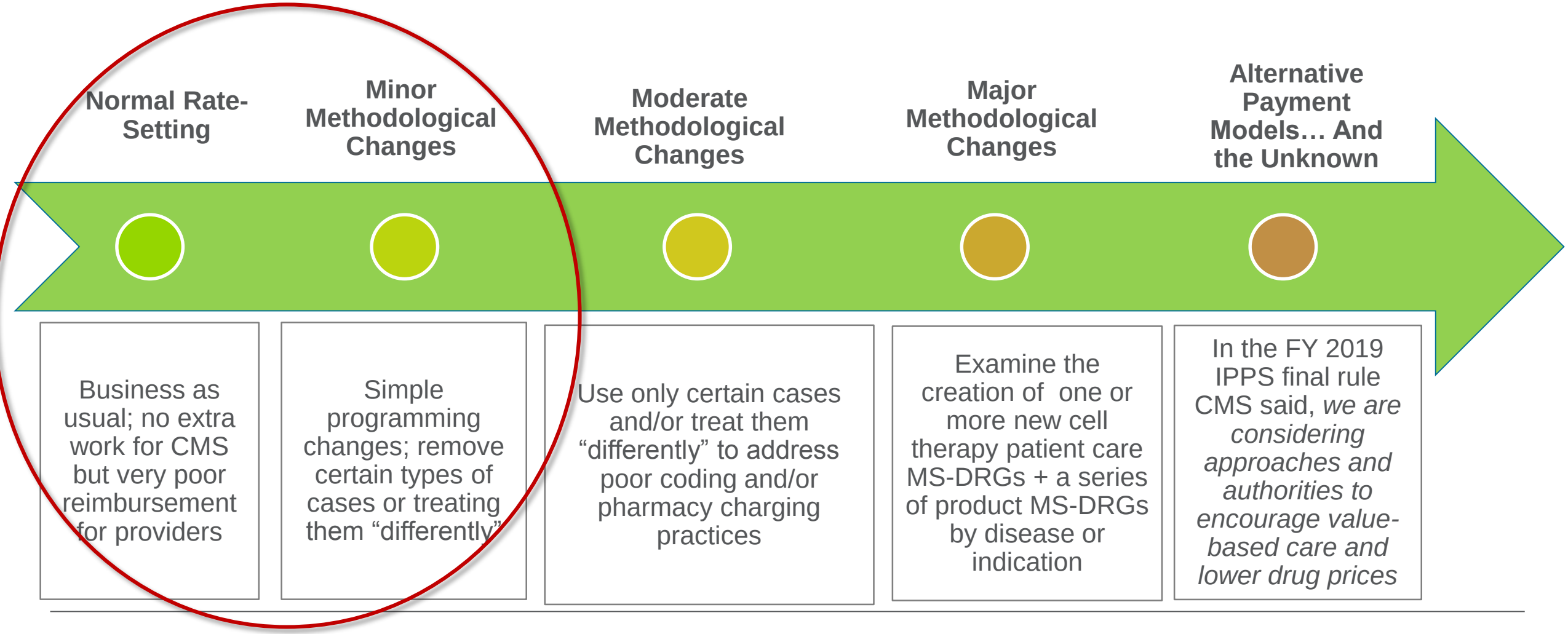
CMS Should...

- Create a new MS-DRG for FY 2021
- Apply the usual adjustments
- Exclude clinical trial cases from rate-setting
- Carve out the product payment from patient care costs
- Extend NTAP until more data is available

CMS Should Not…

- Proceed with the existing MS-DRG 016 assignment
- Do not apply adjustments
- Think it has the authority to do something different with the adjustments

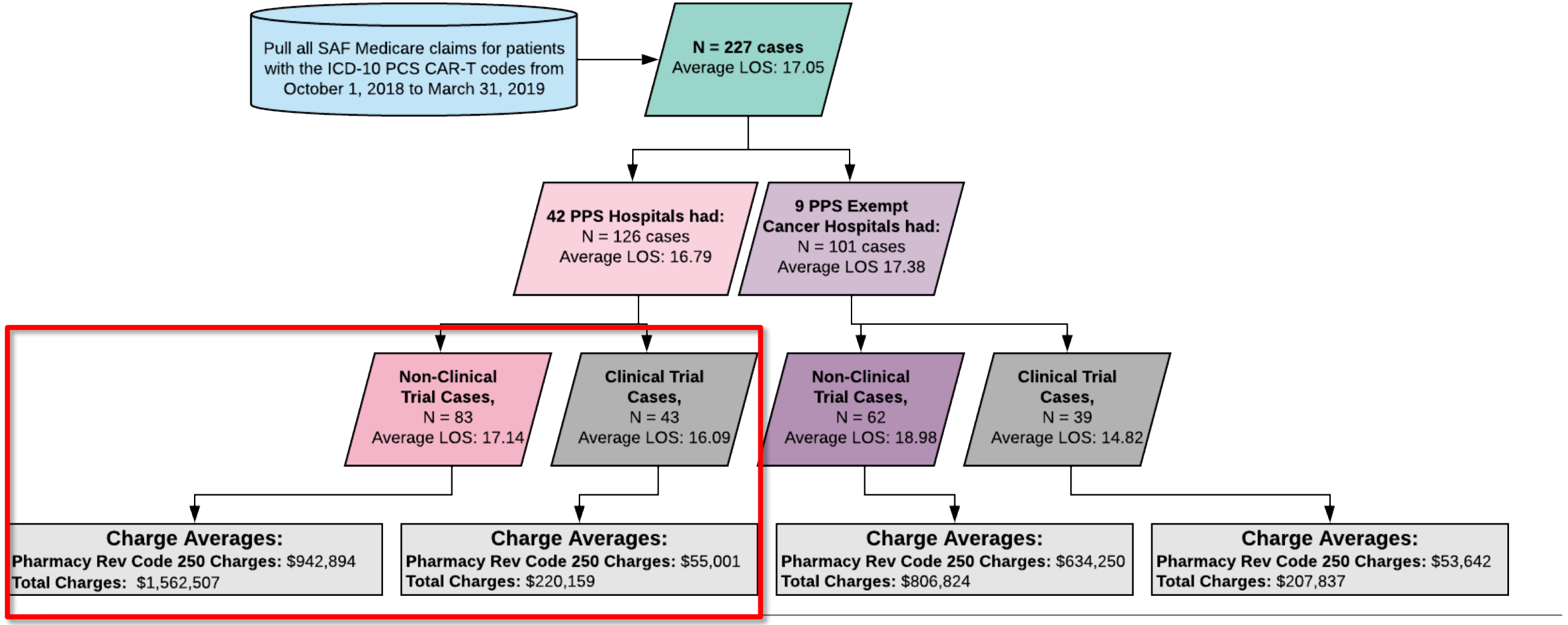
The Great Debate: What Should CMS Do for FY 2021?



MOST of these options depend on provider submitted data to CMS

So what does it look like so far?

Breakdown of FY 2019 SAF Cases



Pharmacy Charge Breakdown: Commercial Medicare CAR-T Product Cases

- 94 of 145 (65%) of commercial cases have drug charges < $1,000,000
  - 24% have charges < $100,000
- Medicare uses provider billed charges for current payment and future rate-setting
  - Medicare will estimate the pharmacy cost of CAR-T claims by multiplying the national pharmacy cost center of 0.191 by the provider's charge
  - .191 x $1,000,000 = $191,000 (CAR-T cost estimate)
- So what providers need to charge so that Medicare can compute a cost from the billed charges of $373,000 would be $1,952,879

Charge statistics for drugs in non-clinical cases of CAR-T
DRAFT -- based on SAF data Q1-Q2 of FY 2019

The FREQ Procedure

Revenue Center Total Charge Amount				
total_charges	Frequency	Percent	Cumulative Frequency	Cumulative Percent
$0-<$100,000	35	24.14	35	24.14
$100,000-<$500,000	22	15.17	57	39.31
$500,000-<$1,000,000	37	25.52	94	64.83
$1,000,000-<$1,500,000	14	9.66	108	74.48
More than $1,500,000	37	25.52	145	100.00

New Data on Claims That We Can Start to Begin Collecting for Cell and Gene Therapies

- GIGO: Garbage In, Garbage Out – Medicare relies on provider submitted data to set rates yet does not provide explicit guidance on how providers should submit charges
- Capturing true cost vs. computing or estimating cost is critical
- New ability exists for CMS to capture cost data on claims but will this occur
- Using the value code is only one part of the data story but it's a start because it will allow comparisons of costs across cases for similar indications, and begin to answer questions about value, downstream cost savings, etc.

Discontinue Value Code
Value: 86
Effective Date: 3/31/20

New Value Codes
a. Value: 87
Categorization: Monetary
Title: Gene Therapy Invoice Cost
Definition: Invoice/acquisition cost of modified biologics. For use with Revenue Category 0892.
Effective Date: 4/1/20

b. Value: 90
Categorization: Monetary
Title: Cell Therapy Invoice Cost
Definition: Invoice/acquisition cost of modified biologics. For use with Revenue Category 0891.
Effective Date: 4/1/20 *(Replaces discontinued Value Code 86)*

New Revenue Code
Value: 0982
Title: Special Processed Drugs - FDA Approved Gene Therapy
Definition: Charges for drugs and biologics for gene therapy requiring specific identification as required by the payer. If using a HCPCS to describe the drug, enter the HCPCS code in the appropriate HCPCS column.
Standard Abbreviation: DRUGS/GENE THERAPY
Effective Date: 4/1/20

Stop #3: Bridging the Gap Between the Current Payment Train and the Payment Policy Platform We Need to Be On

- What will payments for the next set of products look like?
  - Other CARs like multiple myeloma in 2020/2021
  - Other cell therapy products
  - Gene therapy products
- Are changes to NTAP possible?
  - Formula/cap; criteria; time available
- Medicare rarely makes big changes, so how do we get from “here” which is terrible reimbursement to “there” which is an unknown?
  - What are the most likely options exist?
  - What infrastructure is needed at CMS?

Stop #4: Crossing the Chasm

Will CMS ever be convinced that it needs to change its 35+ year old inpatient payment system given the “new branch of medicine”

Stop #4: Crossing the Chasm (Cont.)

- Building a new Medicare payment system will require making considerable changes
- A new “ecosystem” is needed that removes providers and patients from being in the middle
- Can Medicare follow some of the initiatives being tested:
  - Eliminate buy-and-bill and move the risk between Medicare and the manufacturer
  - Payment over-time; installment plan options
  - Performance based models (but what do we measure), rebates, installment plans
  - Models where money can flow/count differently across Medicare pots or the creation of a new pot of money

Summary of Stakeholder Concerns

Medicare Concerns

Funding

Constrained by statues around funding pools, NTAP; CMS looks at the program overall

Lack of data

Clinical & outcomes data, access data, cost off-sets, efficacy, durability

Infrastructure

Existing infrastructure will not support new models; new investments and new ways of thinking along with new laws required

Provider Concerns

Upfront costs

Large purchase prices will cause cash flow problems; consider replacing buy and bill

Unsustainable Losses

Private payer rates on current CARs are not able to offset Medicare's poor reimbursement

Finding Alternative Methods

Clinical trials, move to outpatient; in-house development; non-payment for cell collection/processing becoming a bigger issue

Industry Concerns

Value vs $$$

High value therapies that patients need, costs to develop are high, our price is "right"

Long-Term Costs Lower

Up front costs are high, but downstream costs are averted

Patient Access

Approvals coming but these therapies are only as useful as patients are able to have access

Stop #5: Laying New Track

- How do we convene all stakeholders to come up with new payment models that we take to Medicare to have an honest conversation about where its payment policies need to go?
- What legal/regulatory changes are necessary to support CMS taking a new path forward?
- When will we start to have hard health economics and outcomes research (HEOR) analyses for these therapies?

The Elephant on the Tracks

- Price
  - Minor CMS methodology changes will not fix this issue
  - Everyone has a stake in prices, but there is no one right answer on what the “right” dollar amount is
- Medicare: what if no new track is laid for the pipeline of cell and gene therapies…what if the inertia to make changes continues
- Providers: clinicians who want to provide new therapies being told they cannot due to Medicare inpatient reimbursement problems; unsustainable cash flow issues
- Patients and families: access to life altering approved treatments is a necessity but what if access is denied

Summary

- What are the **best options** for Medicare to provide **fair and equitable payment** to **preserve beneficiary access** in the near term vs. over the longer-term?
- Will Medicare take its cues from other payers and begin **thinking outside the box** or will it be business as usual?
- A **chilling question** - is CMS trying to set a **“defacto” ceiling** on future cell therapy product prices…we’ll have our first preview to the answer to this in April.