

AMCP Market Insights

Multiple Myeloma



Webinar December 7, 2021

AMCP Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.

Multiple Myeloma Market Insights Program
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AMCP Market Insights Overview

- **Association-led research** with AMCP members and non-members at regional and national plans
- **Blinded format** to allow participation and candid feedback
- **Topics are based upon category**, not product, to provide a holistic view of management
- Programs are **focus group meetings or virtual programs** with Clinical Key Opinion leader presentation
- **Current and future treatment options** are addressed to understand clinical and medical management utilization approaches

Market Insights: Multiple Myeloma Treatment Landscape: Today and Tomorrow

Saad Z. Usmani, MD MBA FACP
Clinical Professor of Medicine
Levine Cancer Institute

Panel Questions

Discussion: Treatment Options

Implementing Oncology Protocols

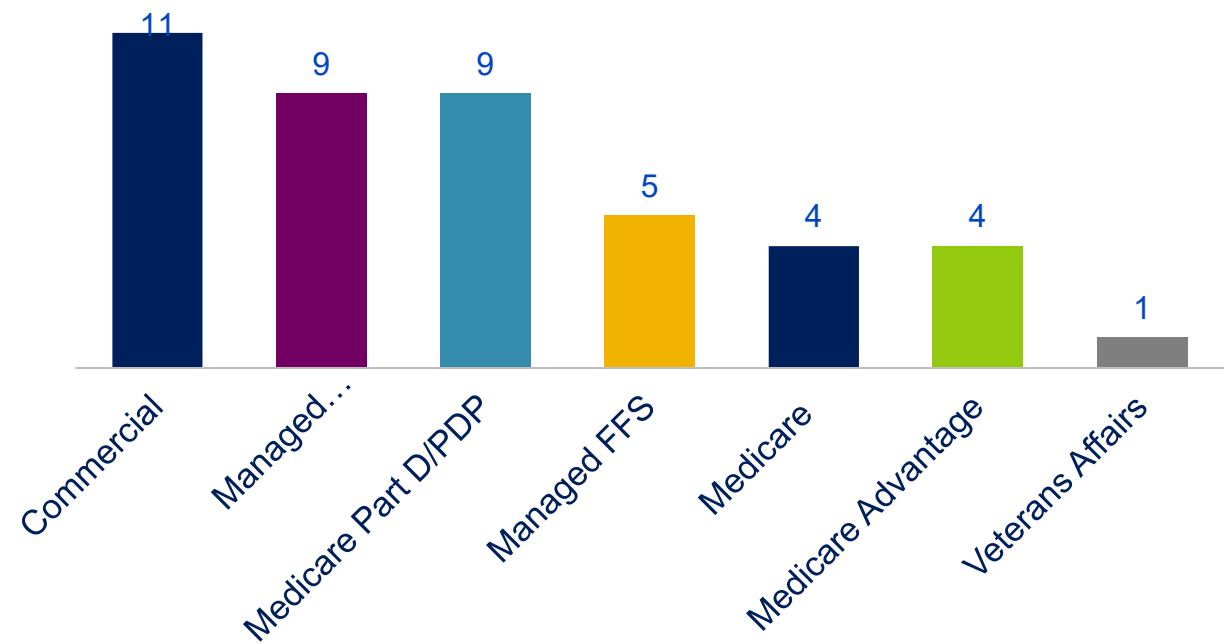
Discussion: Generics and Future

Methodology

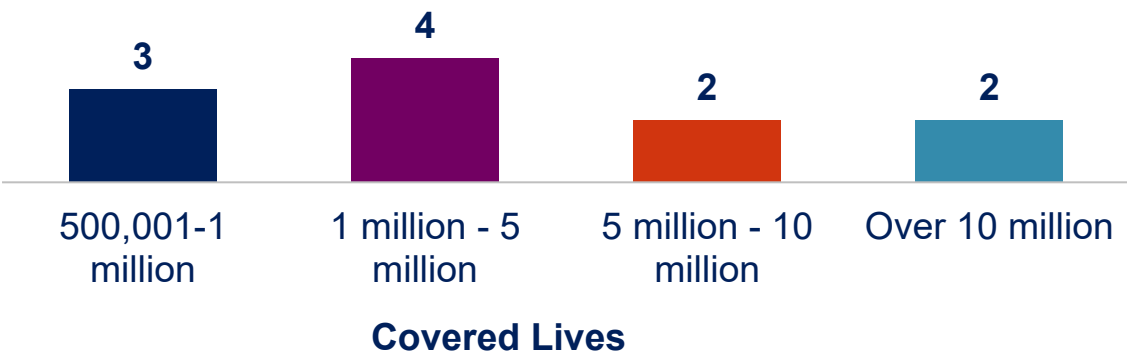
- Five hour virtual meeting on August 26, 2021
- Roundtable format, with presentations and group discussion
- Representing > 30 million covered lives



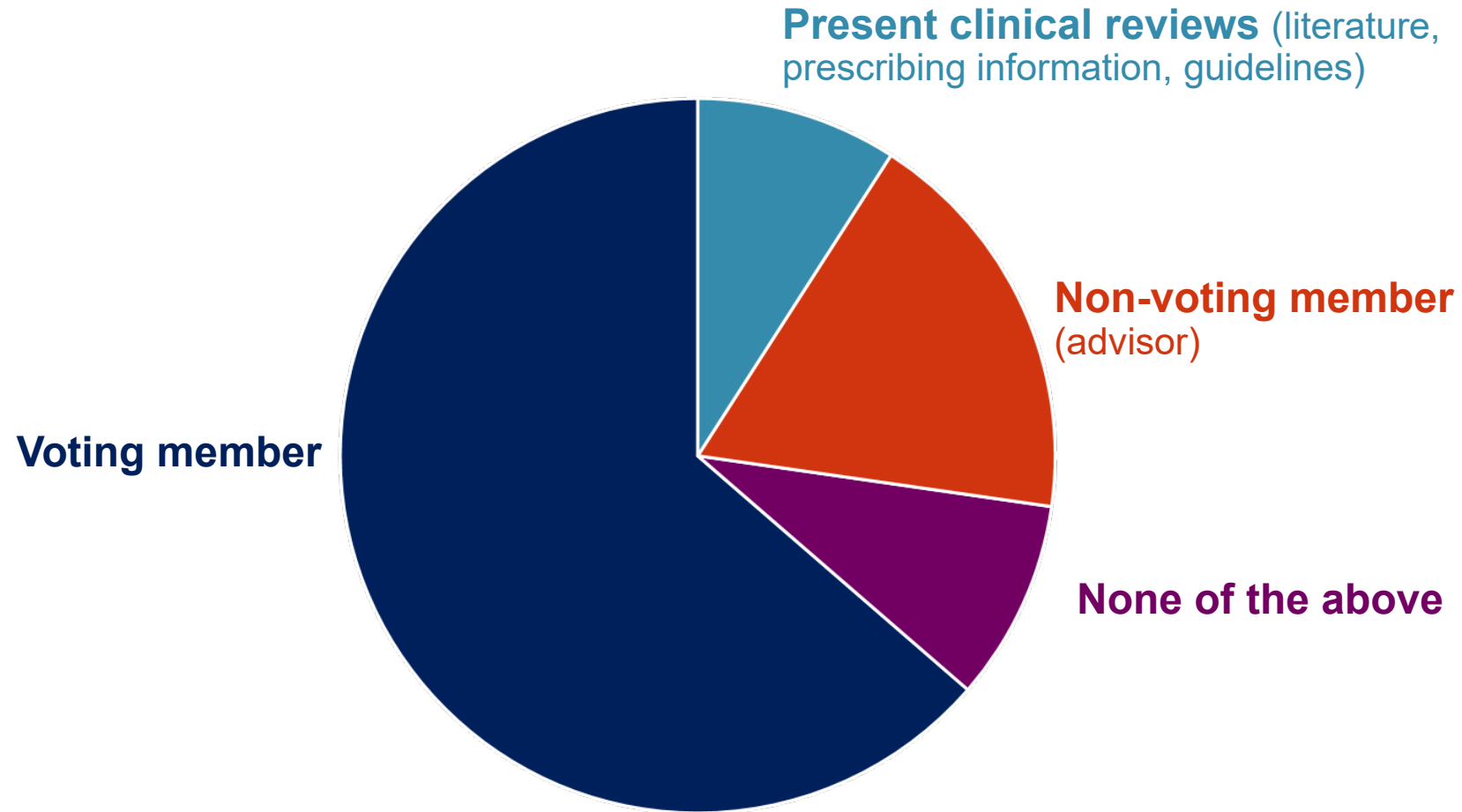
Several books of business are represented



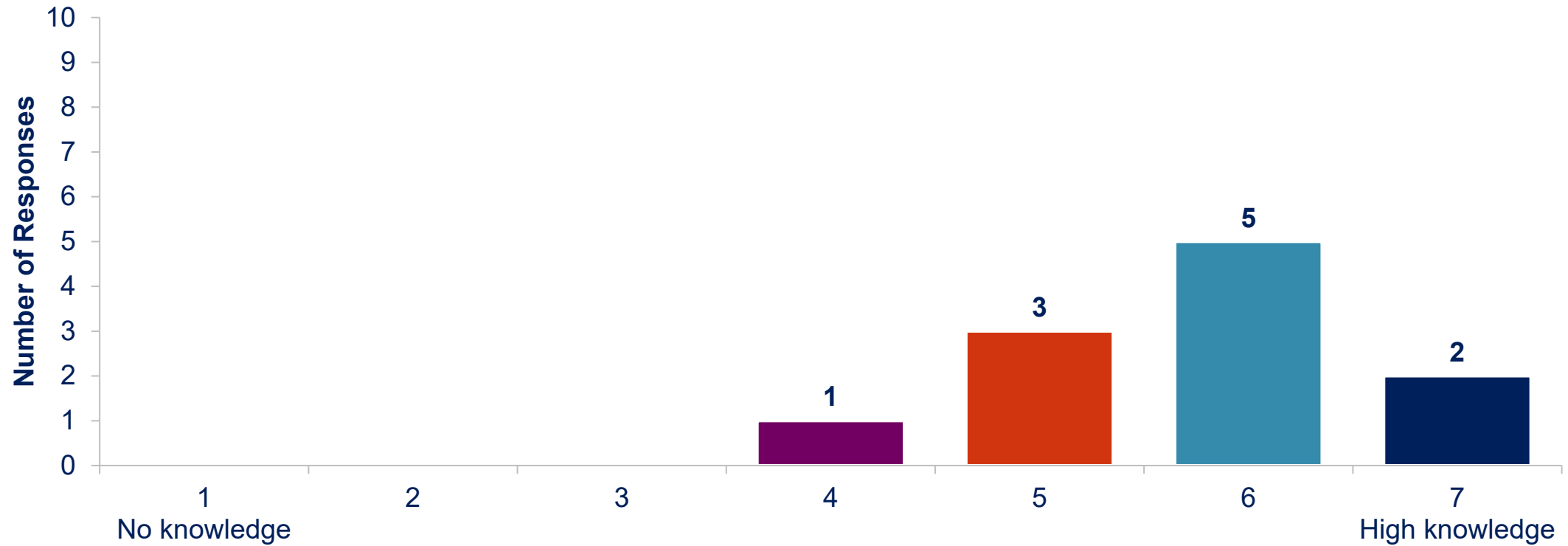
Count of national and regional plans
Between 500,000- over 10 million lives



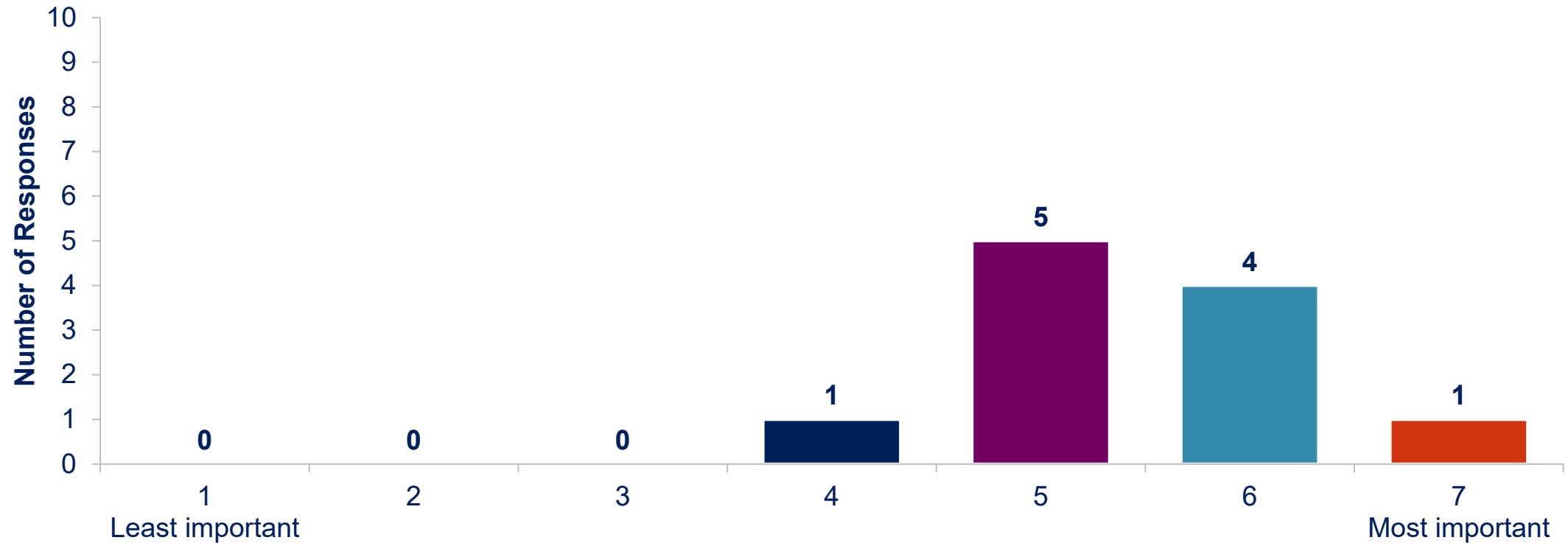
Most participants have a role in P&T meetings



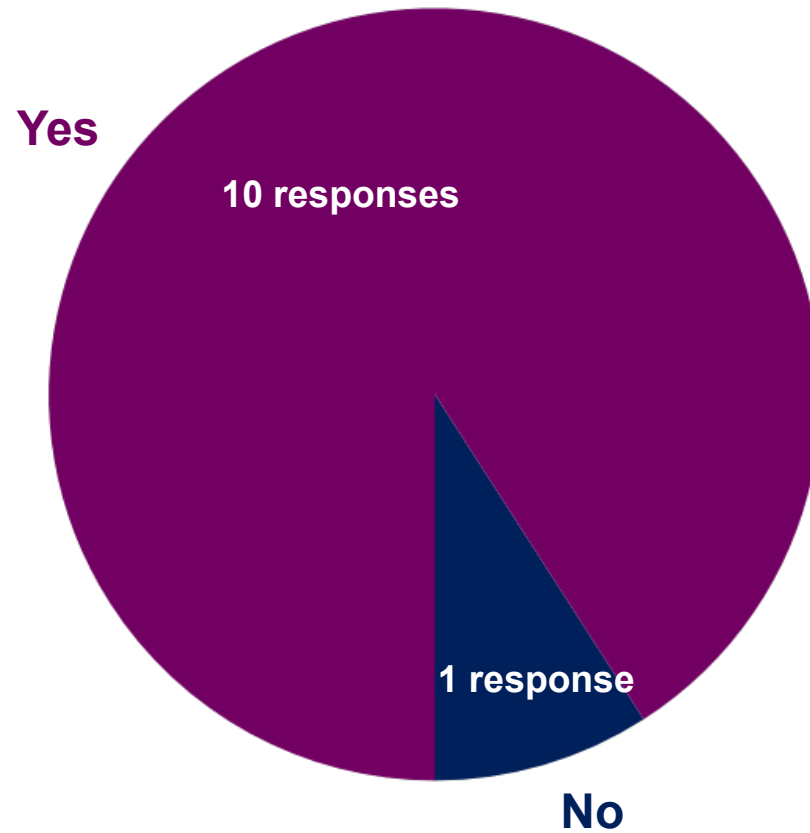
The baseline knowledge of multiple myeloma is relatively high



5-year survival data impacts access and reimbursement decision-making for MM therapies



Multiple myeloma is in the top-5 of all oncology indications for management priority



Objectives

Update on treatment options, update on prognosis of care, update on market dynamics

Value based opportunities to improve care

Understanding the true utilization in Multiple Myeloma by line based on actual utilization and then presented by line of therapy

Helpful to discuss treatment outcomes that are clinically relevant vs. outcomes used in studies that are premature/not fully defined so we can ensure appropriate medication use and lower financial toxicity.

Sharing of PA approval durations

Relapsed Refractory treatments. Evaluating BCMA outpatient therapy vs. BCMA CAR-T

Investigational agents and the extent to which TTP, OS, and RR are impacted

Identifying and instituting pathways

What information or compendia outside of NCCN is commonly used for oncology (including multiple myeloma) management?

It is important for everyone to gain an understanding of how the payer, provider and patient will work together to manage multiple myeloma, what best practices and strategies can be implemented collaboratively to give the best clinical outcomes.

Effective and proactive engagement/management of oncology network, oncology pathways are good assistance in bringing expertise and capabilities

Top Level Insights



Current management approaches for multiple myeloma varies due to recent innovations



Additional evidence is needed around innovative therapies



Clarity is needed around sequencing of treatments in multiple myeloma



Total cost of care in multiple myeloma is important, especially related to treatment side effects

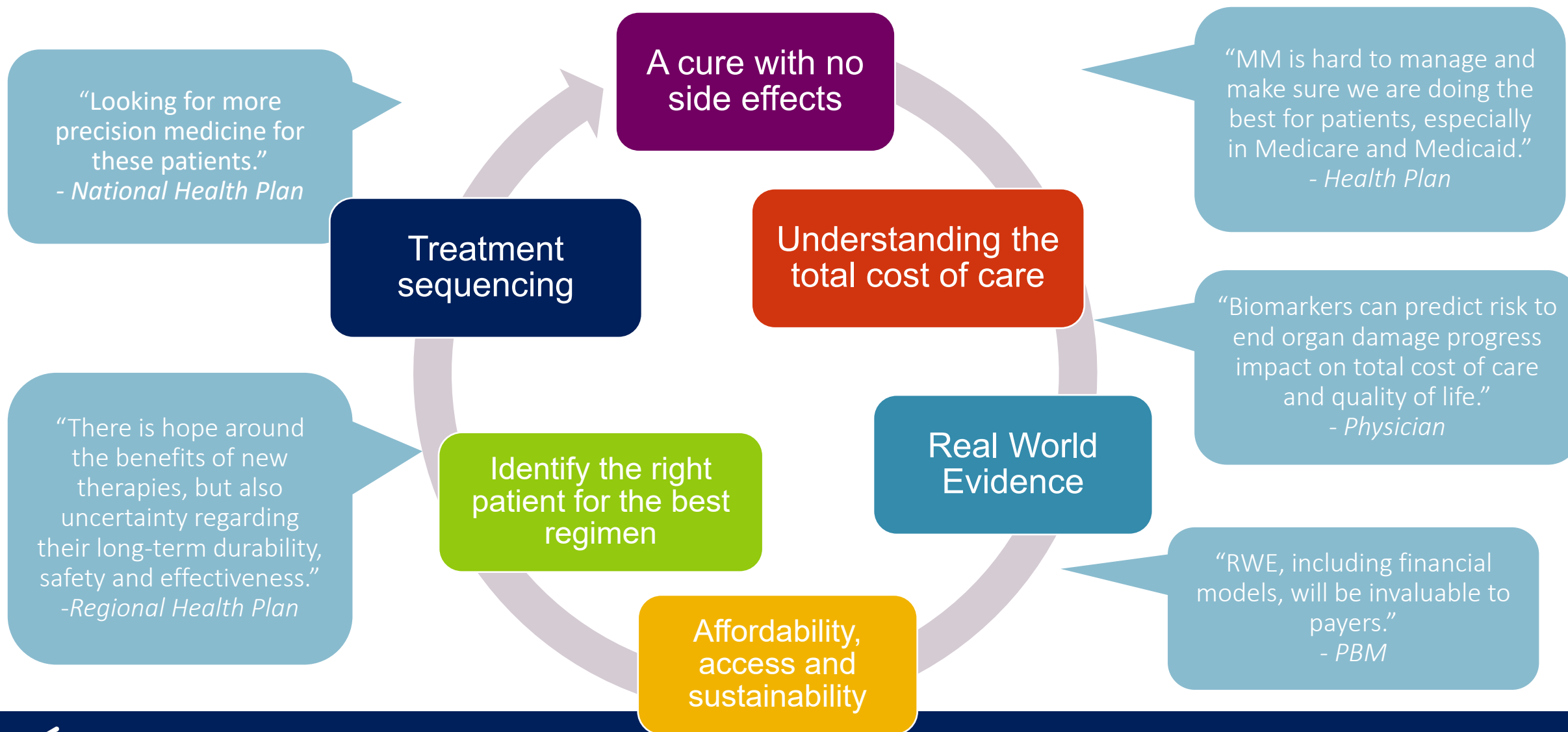


Payers, IDNs and employers are innovating to better manage multiple myeloma care



Need collaborative partners to address financial risk and improve access

Payer Identified Unmet Needs in Multiple Myeloma



Multiple Myeloma

- Estimated to afflict approximately 150,000 Americans. Primarily a disease of older adults.
- Hematologic cancer of plasma cells. Uncontrolled proliferation of plasma cells leads to a variety of clinical presentations
- Multiple Myeloma is most often diagnosed through a bone marrow biopsy showing $\geq 10\%$ plasma cells
- Mainstays of current treatment include immunomodulatory agents, proteasome inhibitors and anti-CD38 monoclonal antibodies
 - Not curative and most patients eventually relapse
 - The last 15 years have seen a proliferation of new therapies for Multiple Myeloma, resulting in improvements in survival

“We need to recognize that multiple myeloma is not one disease.”
- Physician

“Oncology spend and trend is #1 on the radar for payers.”
- National Health Plan

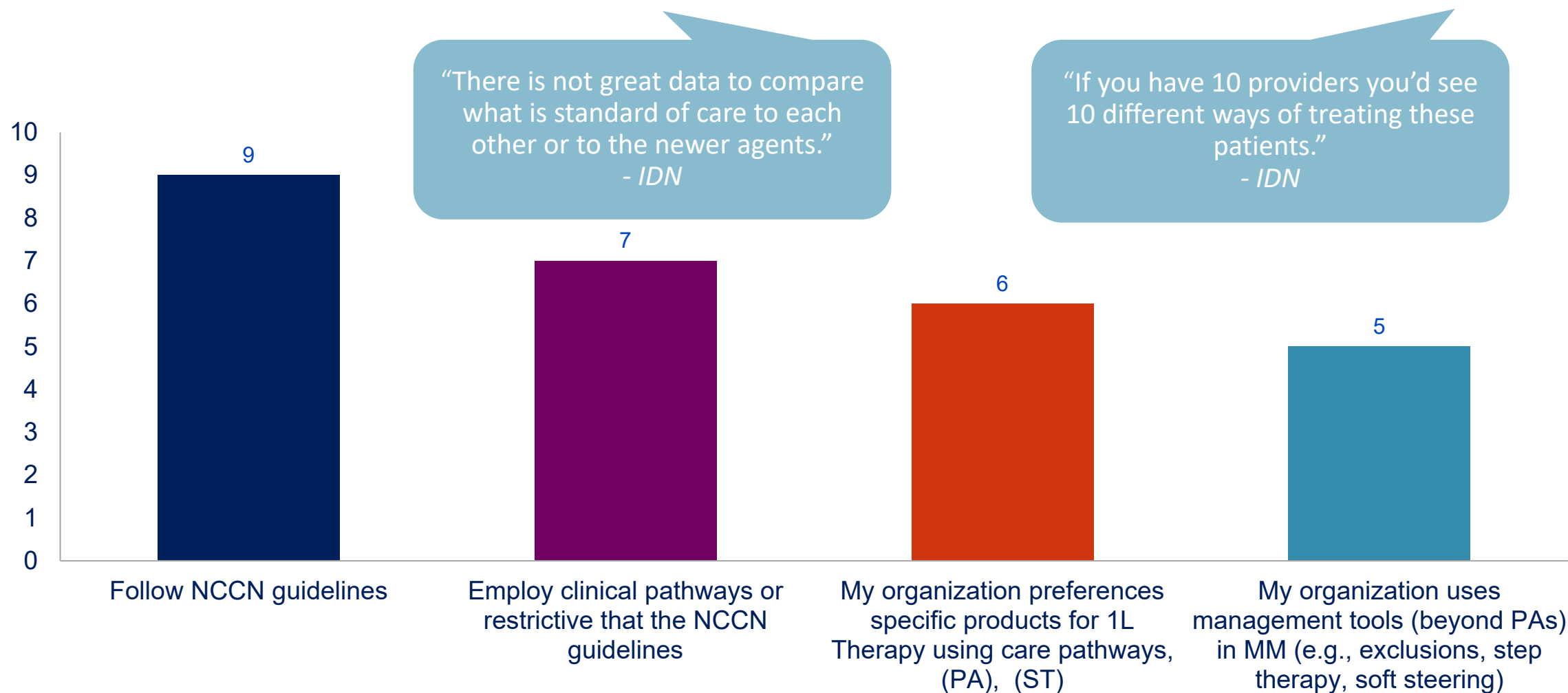
“Combination chemotherapy is needed for optimal disease control.”
- Physician

Goals of Myeloma Treatment

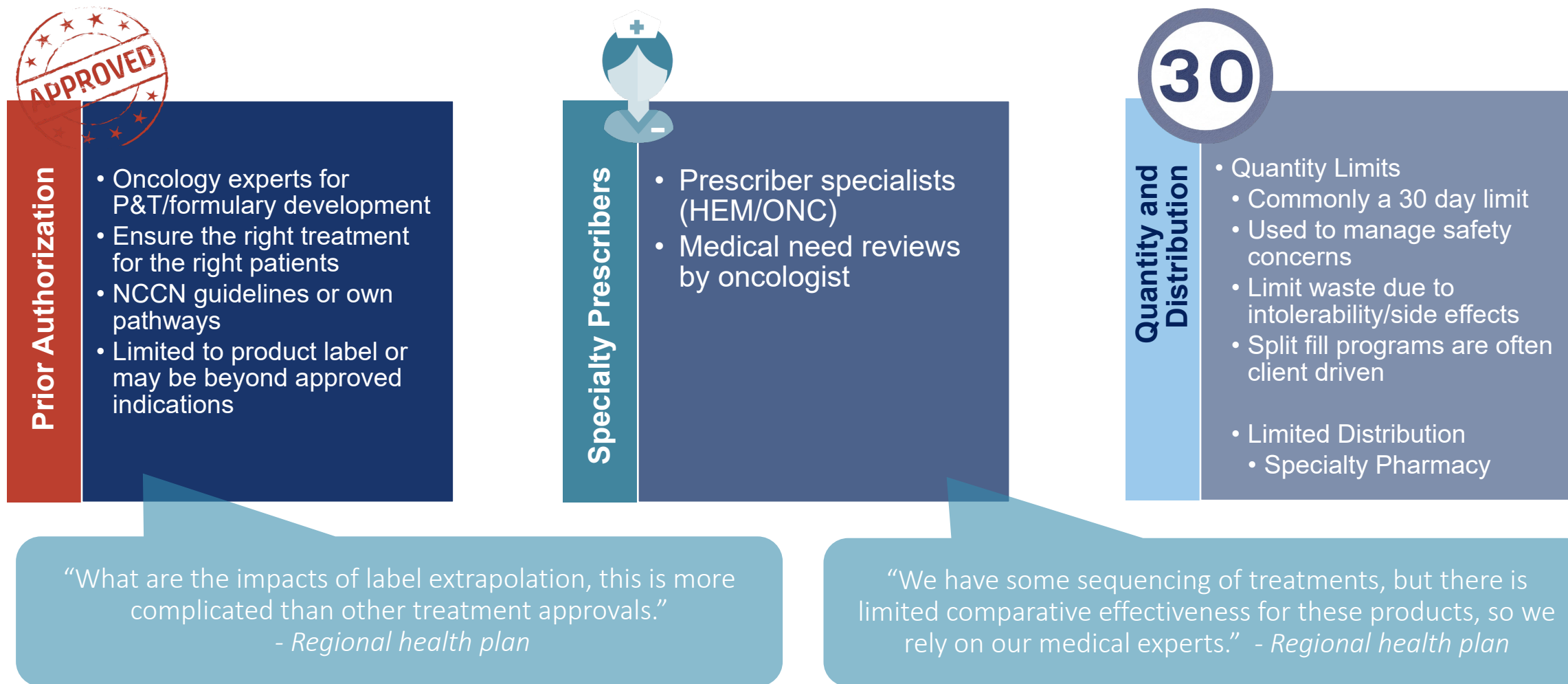
- Reduce disease burden with induction therapy
 - Reverse disease-related complications
 - Deep and durable response (MRD negativity better than CR)
 - Not interfere with stem cell collection, if needed
- Prolong durability of response with maintenance therapy
 - Delay disease progression
- Reduce/ minimize/ manage toxicity
 - Balance quality of life
- Extend overall survival
- Ultimate goal is long term disease control and possible 'cure'



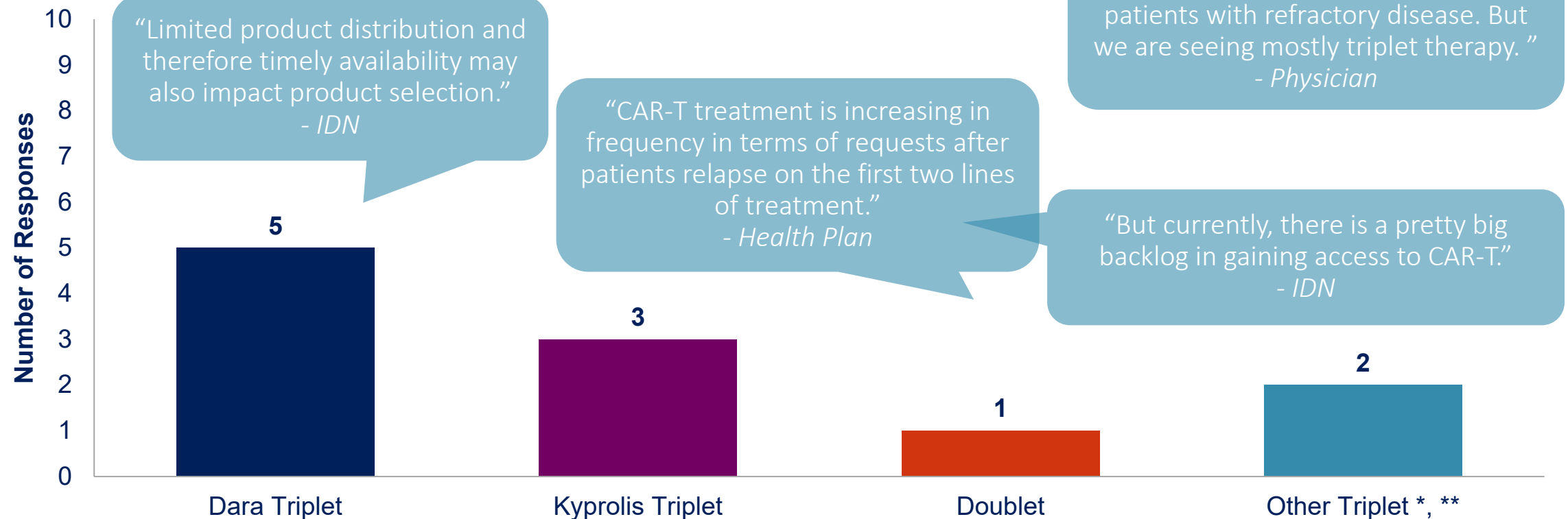
Current Management Approaches For Multiple Myeloma Varies



Most Payers Are Using Traditional UM Tools To Manage Cost Trends & Treatments



Payers Are Seeing A Variety Of Treatment Options For Relapsing/Refractory Multiple Myeloma



*Depends of what was used in prior lines of therapy

** Not specified

Emerging Treatments

“Patients may develop resistance to treatment, so novel therapies with new mechanisms of action represent important clinical options.”
- *Health Plan*

“How do we manage the side effects in refractory patients? There are a lot of side effects from treatments.”
- *IDN*

“Are CAR-Ts really one shot and we are done?”

“There is hope around the benefits of new therapies, but also uncertainty regarding their long-term durability, safety and effectiveness.”
- *Regional Health Plan*

Chimeric antigen receptor T cells (CAR-T) and bispecific antibodies (BsAb) represent a new wave of treatments

- Toxicities: cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), and low blood counts, all of which are treatable
- High upfront investment, uncertainty surrounding long-term durability, and adverse events have led to some concerns among payers
- Treatment selection and sequencing become increasingly complex with the increasing number of therapeutic options, including antibodies

More Evidence Is Needed Around Innovative Therapies

Clinical Trial Design

- Overall survival is the **gold standard** of clinical end points, but it requires a larger sample size and longer follow-up
- Minimal residual disease (MRD), overall response rate, complete response rate, and stringent complete response may be useful as surrogate end points to estimate progression-free survival benefit for patients with newly diagnosed multiple myeloma
- Payers are questioning if we should still be looking at surrogate endpoints in Multiple Myeloma given the available treatment options
- There is an opportunity to use more real-world data to better understand treatment effects

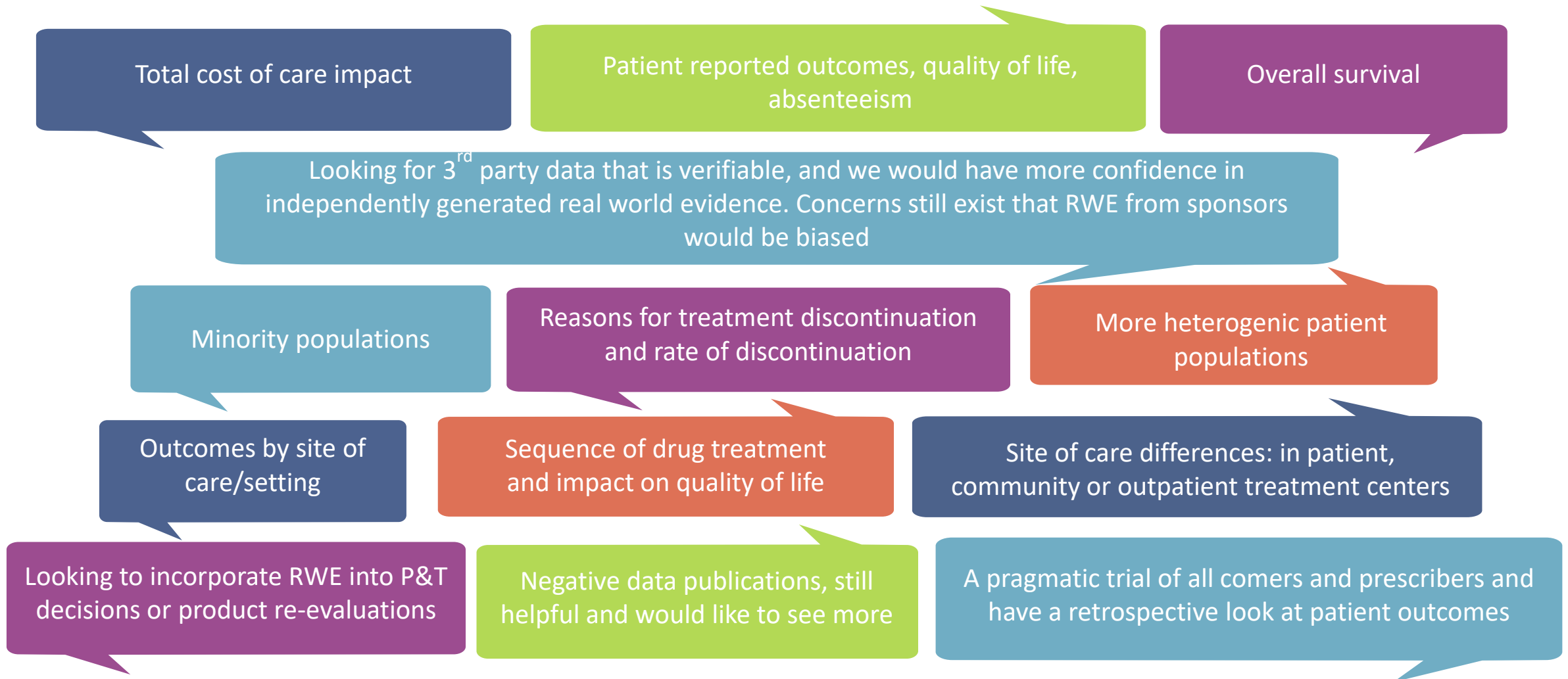
“We have so many options for MM now, should we be still be looking at surrogate endpoints?”
- IDN

“Being a bit more rational in terms of strategy in developing clinical trials is important. The use of surrogate endpoints is imperfect...”

“There is real-world data to support that MRD negativity is a “viable surrogate for PFS” in multiple myeloma.”
- Physician

More Evidence Is Needed Around Innovative Therapies

Real World Evidence



Payers Are Innovating to Better Manage Multiple Myeloma

Implementing disease state working groups to advise on complex disease states

- Multi-disciplinary
- Inform P&T decisions
- Monitor trends
- Support custom pathway development and maintenance; treatment sequencing
- Allows payers to consider evolving evidence more quickly and look beyond guidelines only for pathway development
- Support review of off-label use requests

“There remains a big-time question on when to stop treatment/care and brings forward the importance of hospice, palliative care and shared decision making.”
- *Regional Health Plan*

Payers Are Innovating to Better Manage Multiple Myeloma

Starting **generic first** step edits (e.g. bortezomib) to maximize product cost savings on new to market generic treatment options

3rd party management for IV oncology products

Interest in developing **Preferred Formulary** Status

- Based on physician experts, literature, guidelines
- Influenced by contracting strategies, site of care, infusion volume vs SQ, chair time in infusion clinic, heterogeneity of disease, provider groups, and specific patient characteristics

“We are currently focused on developing preferred products for one cancer and will expand preferred status into other cancer types from there.”

- *Regional Health Plan*

“There is less traction in PBMs and non-integrated systems on going preferred with one product.”

- *PBM*

IDNs Are Innovating to Better Manage Multiple Myeloma

“Part of the justification for investing in cellular lab technology is reducing the total cost of care and improving supply.”
- IDN

“When you figure it out, we would be interested in sending our CAR-T patients to you.”
-Health Plan

- Focusing on the total cost of care
- Developing in house cellular lab/tech programs to make their own CAR-Ts
- Synchronizing care across provider groups
- Integrating treatment pathways into electronic medical records (EMR)

“It is not just acquisition cost, but it is the total cost of care, and you need to be looking at patient outcomes too.”

- IDN

IDNs Are Innovating to Better Manage Multiple Myeloma

- Seeking early feedback and buy-in from providers in new policy development
- Launching site of service programs in oncology
- Biosimilar strategies
- Data is key
- Robust education to clinicians


“We are seeing site of service strategies in the market: with mixed push back from providers or patients.”
- IDN



Employers Are Innovating to Better Manage Multiple Myeloma

Carving out Multiple Myeloma Medications from Benefit Coverage

Carve-out

- 
- Covered benefit administered by a third-party vendor
 - Prior authorization and coverage rules are separate from the PBM
 - Drug formulary, or list of covered specialty drugs, does not apply
 - Affects network rates, rebates, and other cost-savings programs in place with the PBM
 - Coverage is not guaranteed for carved-out products
 - Provides greater access to useful medical pharmacy claims data, more transparency into their pharmacy benefits
 - Greater understanding and control of spending, negotiate better deals

“Employers are asking for every option to better manage specialty medications. And you better be able to show you have ticked all of the boxes: UM, specialty distribution, quantity limits, PA etc.”
- *Regional Health Plan*

“There are employers who are looking at alternate funding, where they will exclude the drug from coverage and force a member to find an alternate funding solution.”
- *PBM*

J Manag Care Spec Pharm. 2020;26(10):1317-24, <https://www.rxbenefits.com/blogs/excluding-or-carving-out-specialty-drugs-what-employers-need-to-know/>

Employers Are Innovating to Better Manage Multiple Myeloma

Exclude Multiple Myeloma Medications from Benefit Coverage

Excluded Benefit

When a medication is excluded from the covered benefit, the member is on their own to cover the expenses

- Coded to reject claims as not covered
- Drug discounts are impacted and may not be applied
- Affects patient's out-of-pocket costs and access
- Need-based funding may be impacted
- Leads to more custom benefit administration
- Impact ability to request an exception or medical necessity
- Emerged as a powerful tool to gain additional negotiating leverage
- Exclusion is now moving into the Medicaid program


"In a mandated oncology state... unless it is a benefit exclusion from a self-funded group... you have to cover FDA approved oncology drugs in NCCN guidelines... the benefit design here is dictated by the state."
- Health Plan

"Employers simply cannot afford this..."

"There is no longer a clinical review – it is a benefit exclusion. They seem willing to take the PR hit"
- Regional Health Plan

J Manag Care Spec Pharm. 2020;26(10):1317-24, <https://www.rxbenefits.com/blogs/excluding-or-carving-out-specialty-drugs-what-employers-need-to-know/>.
<https://www.drugchannels.net/2021/03/the-big-three-pbms-ramp-up-specialty.html>

Seeking Collaborative Partners To Address Risk And Access

- 
- Alternative payment models to spread financial risk
 - Value based contracting option –would help support utilization and treatment sequencing
 - Implementation remains a challenge
 - Risk sharing is needed
 - Payers and employers cannot afford risk
 - Similar to the EMBARK program
 - Trying other options before going to most expensive treatments, since they are not curative
 - ICER reports are helpful in evaluating cost effectiveness
 - Reduce health inequities
 - Access for underserved patient populations
 - Travel nurses to improve care coordination and identify insecurities

Opportunities for Improvement

Increase



- 1 Early, competent, transparent sharing of clinical and product information
- 2 Ease of navigation and communication around patient assistance programs
- 3 Willingness to collaborate and share data around subsets of patient populations
- 4 Discussions around payers strategic priorities

Opportunities for Improvement

Leverage

5

Pre-Approval Information Exchange (PIE)

6

Value based contracting agreements and streamlined agreements to decrease complexities

7

Your understanding of the clinical and comparative data to help payers make informed treatment sequencing

8

Real world evidence and clinical outcomes that matter to payers and patients

Questions

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