THE IMMUNO-ONCOLOGY TRANSFORMATION:

Implications for Managed Care

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Live Webcast

Welcome

Jeffrey D. Dunn, PharmD, MBA
Vice President
Clinical Strategy and Program and Industry Relations
Magellan Rx Management

Agenda

Pre-Activity Learning Assessment and Opening Comments/Overview **Jeffrey Dunn, PharmD, MBA**
Assessing the Clinical Benefits and Appropriate Use of Immuno-Oncology Agents **Joan H. Schiller, MD**
Medical and Pharmacy Benefit Design Strategies for Immuno-Oncology Agents **Jeffrey Dunn, PharmD, MBA**
Health Plan Strategies to Enhance Patient Outcomes with Immuno-Oncology Agents **John Fox, MD, MHA**
Audience Q&A Session
Key Takeaways and Closing Comments; Post-Activity Assessment and Evaluation
Adjournment

Learning Objectives

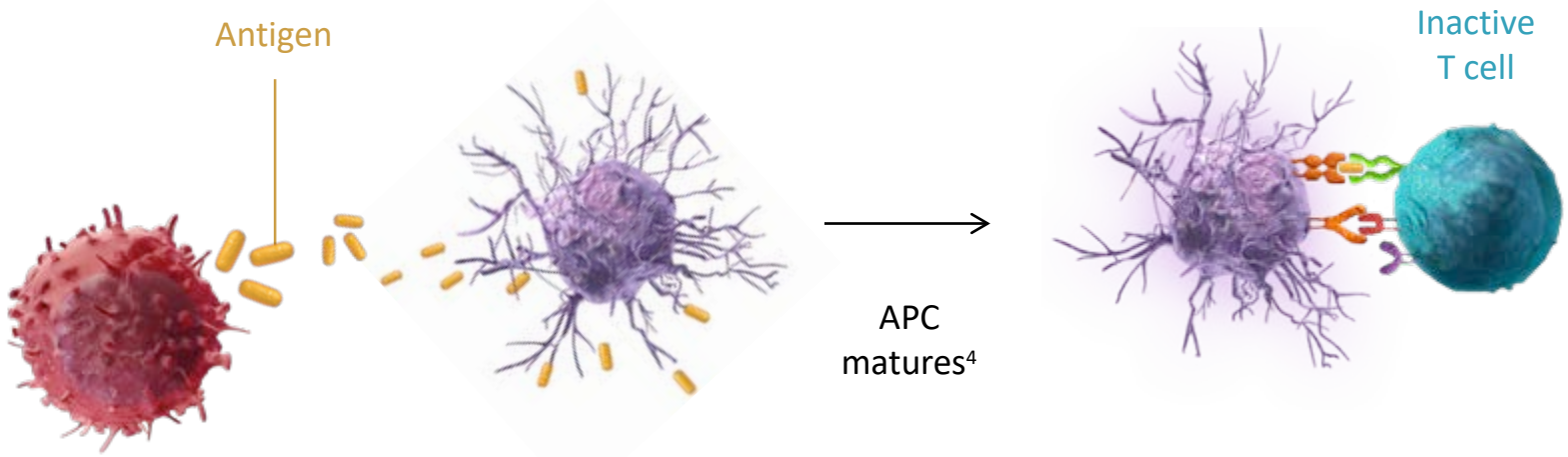
- Characterize the role of the immune system in immunosurveillance and elimination of malignant cell lines with respect to cancer immunoediting
- Describe the mechanisms of action of novel immuno-oncology agents such as PD-1 and PD-L1 inhibitors and CAR-T therapies
- Describe key outcomes measures in immuno-oncology and characterize the importance of cumulative assessment of outcomes
- Apply comprehensive analyses of clinical trial data pertaining to recently approved and investigational PD-1/PD-L1 inhibitors and CAR-T therapies
- Characterize the incongruent application of traditional payer cost-sharing and benefit design approaches to the management of innovative immuno-oncology agents
- Evaluate current and proposed payer initiatives for the funding and management of PD-1/PD-L1 inhibitors and CAR-T therapies

Assessing the Clinical Benefits and Appropriate Use of Immuno-Oncology Agents

Joan H. Schiller, MD
Professor
University of Virginia

T-cell activation: tumor-associated antigens

Tumor-associated antigens can trigger a tumor-specific immune cell response:



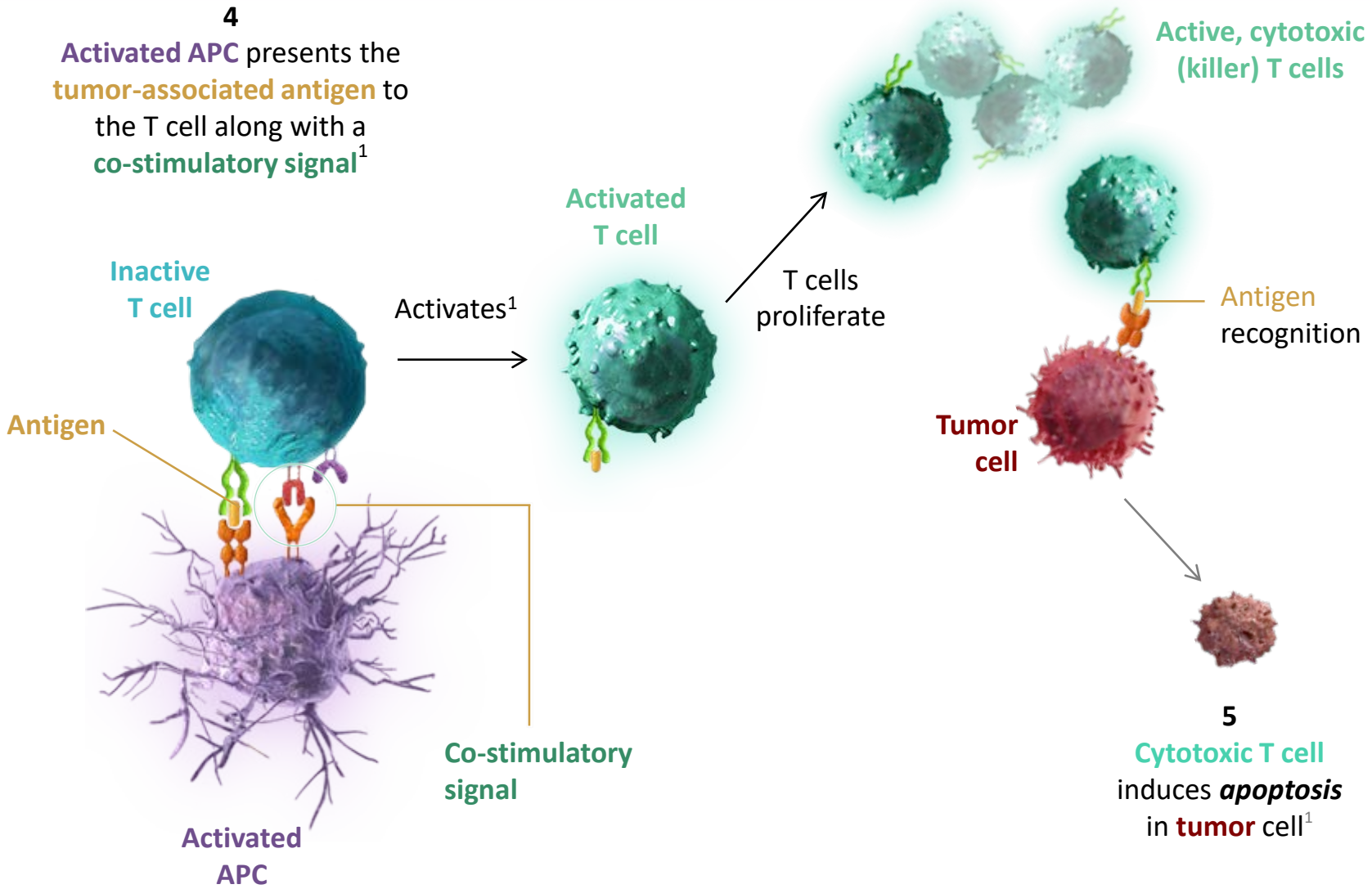
1
Tumors express a multitude of proteins, known as **tumor-associated antigens**[1,2,3,4]

2
Antigen presenting cell (APC) captures **tumor-associated antigens**[2]

3
Activated APC can interact with T cells[4]

1. Pardoll DM. The blockade of immune checkpoints in cancer immunotherapy. *Nat Rev Cancer*. 2012;11:252-264 2. Mellman I, Coukos G, Dranoff G. Cancer immunotherapy comes of age. *Nature*. 2011;480:480-489 3. Heemskerk B, Kvistborg P, Schumacher TNM. The cancer antigenome. *EMBO J*. 2013;32(2):194-203 4. Boudreau JE, Bonehill A, Thielemans K, Wan Y. Engineering dendritic cells to enhance cancer immunotherapy. *Mol Ther*. 2011;19(5):841-853

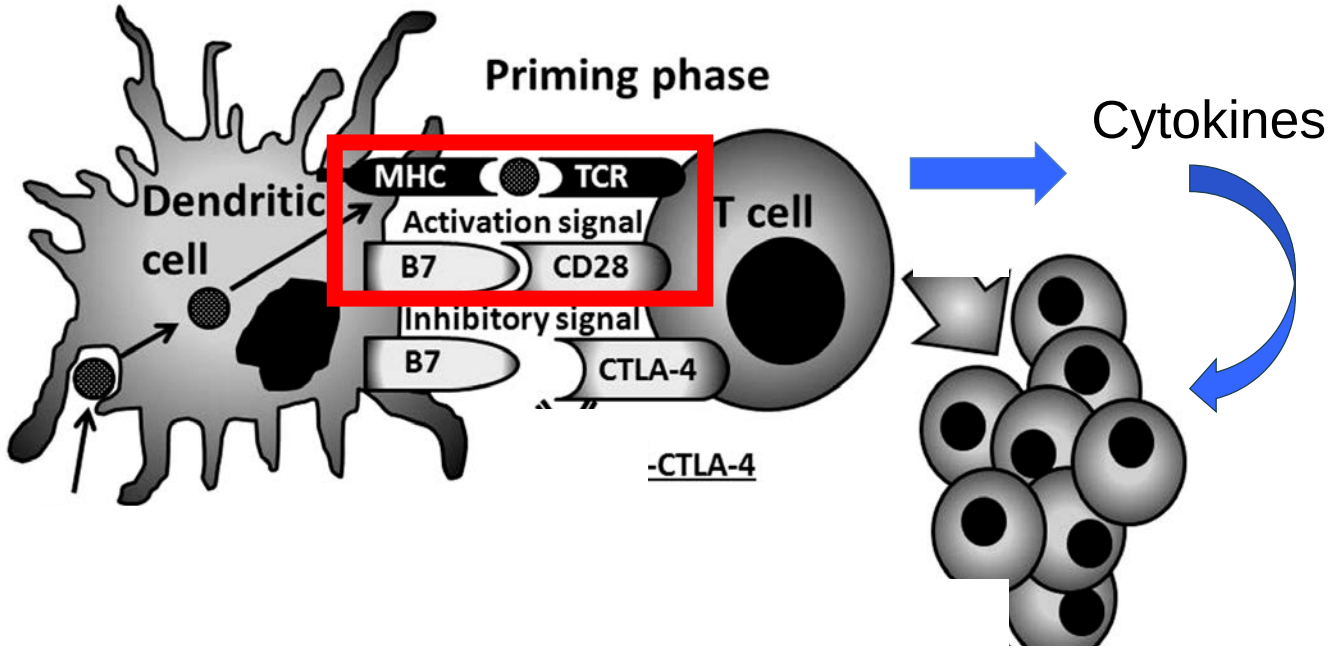
T-cell activation: cytotoxic T cells



1. Janeway CA, et al. Immunobiology: The Immune System in Health and Disease. 6th ed. New York, NY: Garland Science; 2004

How Does T-Cell Activation Happen?

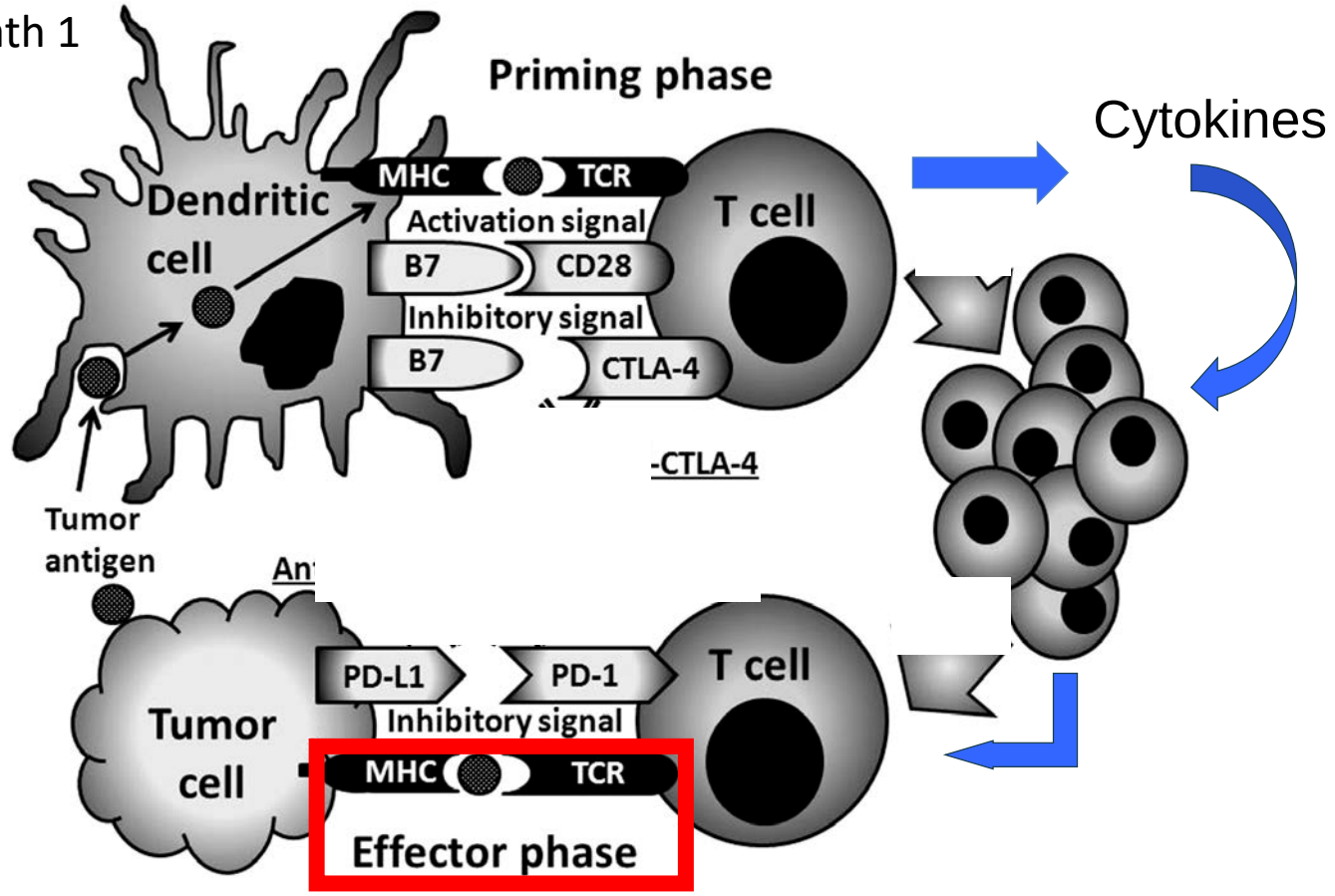
Lymph Nodes



Fumito, Chang. Surg Oncol Clin N Amer 2013;22:765-783

Activated T Cells → Recognize Tumor Associated Antigens on Tumor Cells

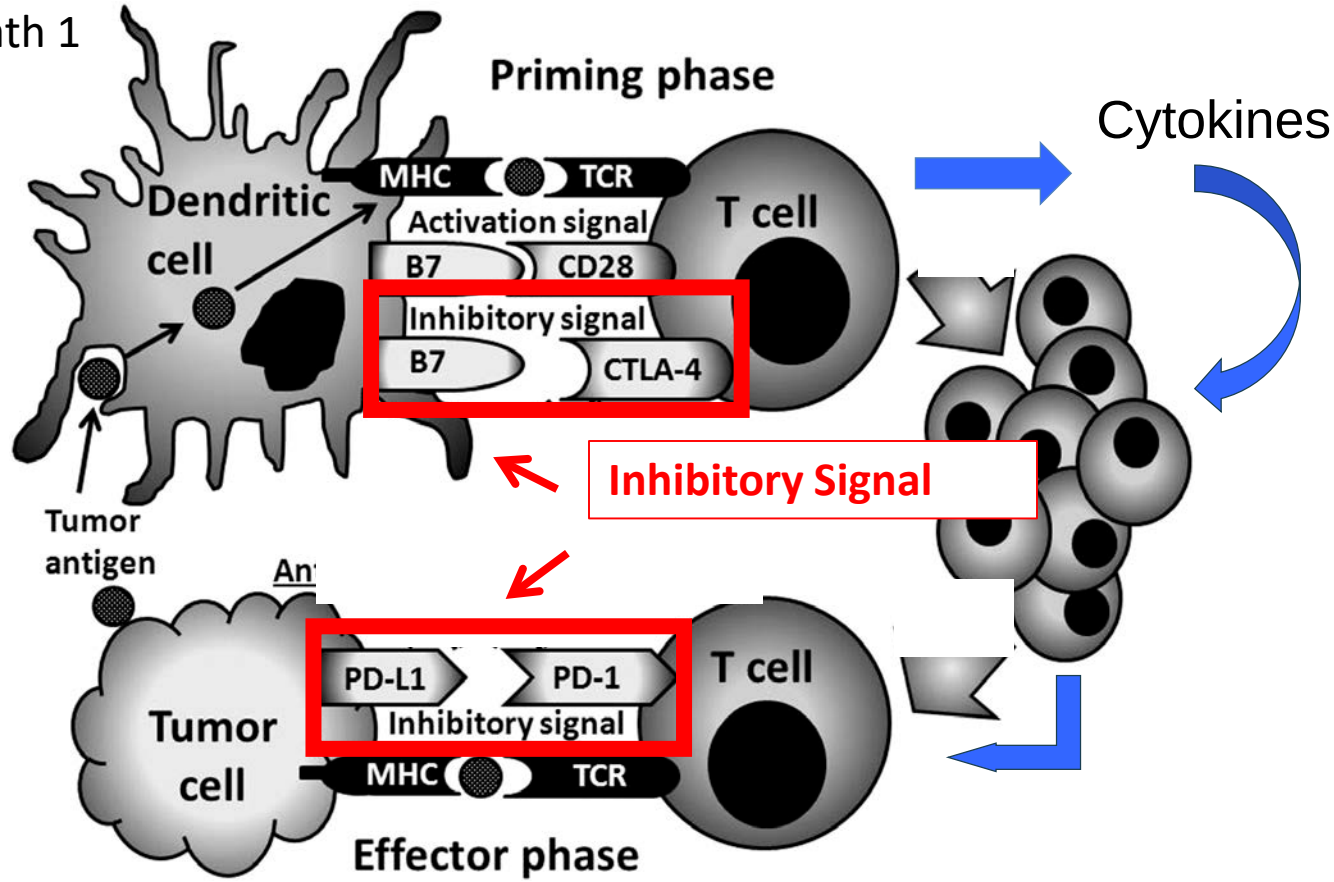
CTLA4: Cytotoxic T lymphocyte antigen 4
PD-1: Programmed death 1
PD-L1: PD ligand 1



Fumito, Chang. Surg Oncol Clin N Amer 2013;22:765-783

Turning It Off…. Need to dampen down the immune system to keep it from running wild and to prevent autoimmune diseases

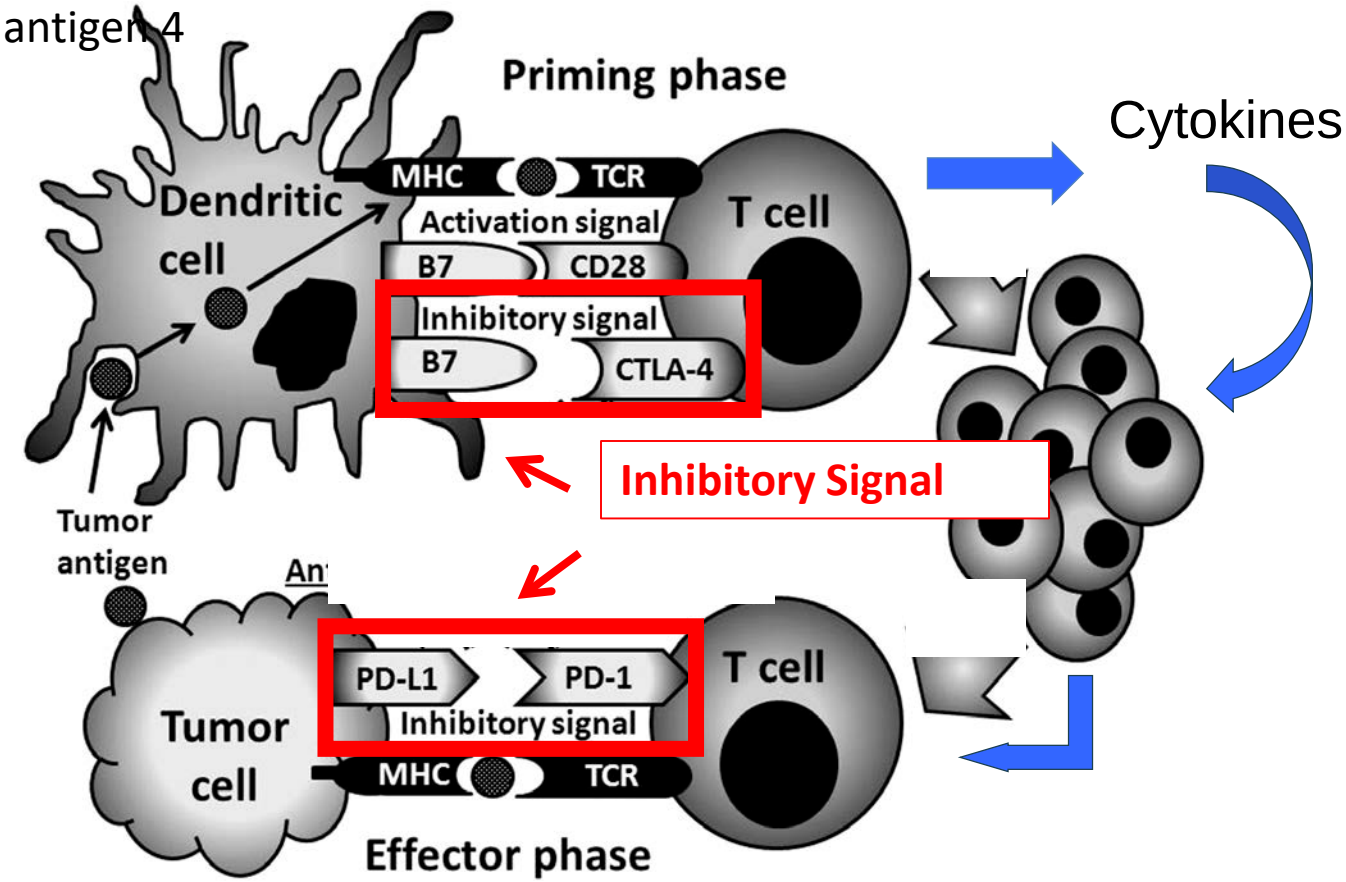
CTLA4: Cytotoxic T lymphocyte antigen 4
PD-1: Programmed death 1
PD-L1: PD ligand 1



Fumito, Chang. Surg Oncol Clin N Amer 2013;22:765-783

So What Goes Wrong? CTLA-4 and PD-1/PD-L1 Inhibit Anti-tumor Immune Responses by
-- Preventing Activation of the T Cells (CTL-4) AND/OR
---Preventing Recognition of the Tumor cell

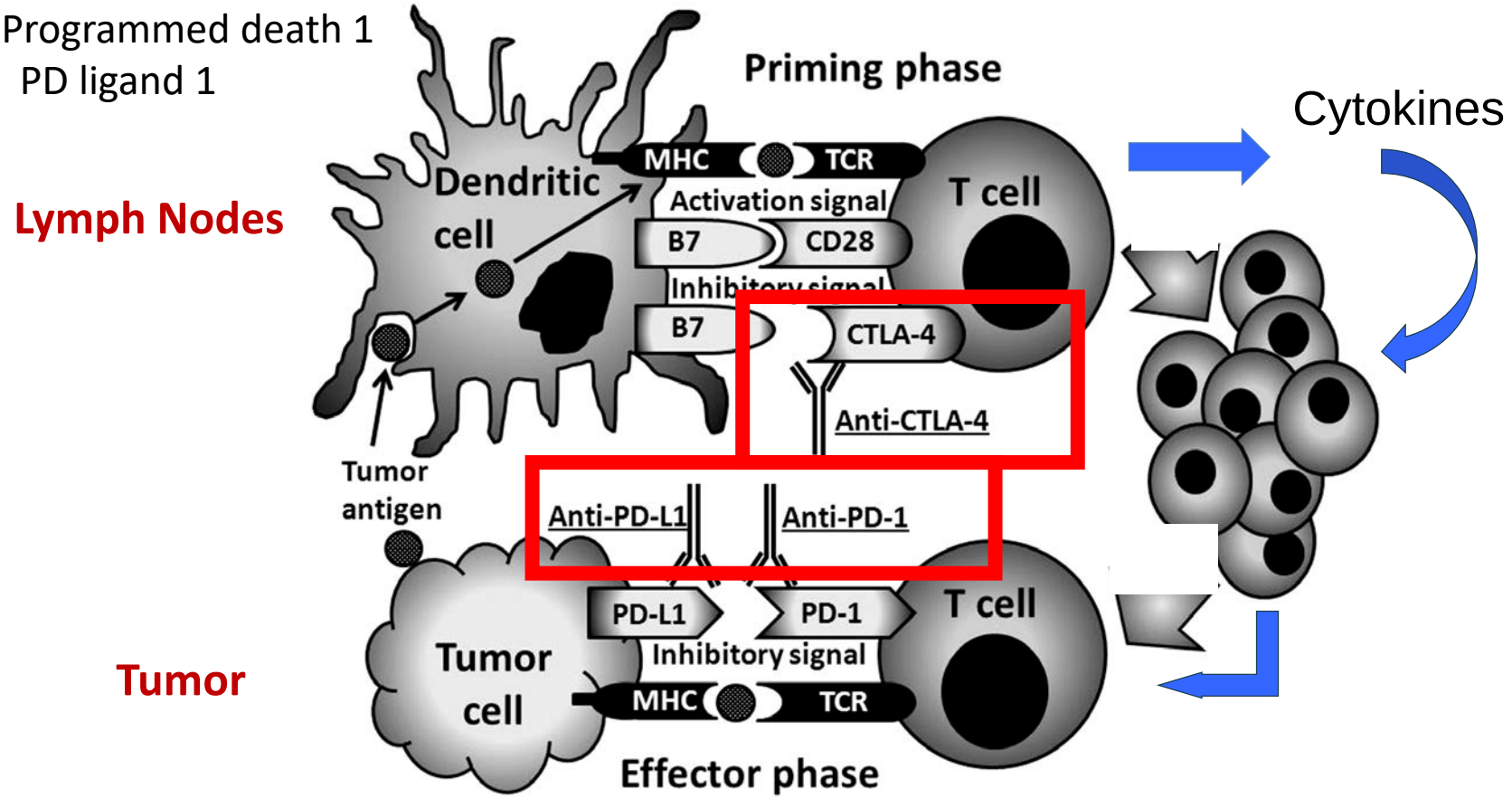
CTLA4: Cytotoxic T lymphocyte antigen 4
PD-1: Programmed death 1
PD-L1: PD ligand 1



Fumito, Chang. Surg Oncol Clin N Amer 2013;22:765-783

So What to Do?
Inhibit CTLA4 (Ipilumumab)
OR Inhibit PD1 or PDL1

CTLA4: Cytotoxic T lymphocyte antigen 4
PD-1: Programmed death 1
PD-L1: PD ligand 1



Fumito, Chang. Surg Oncol Clin N Amer 2013;22:765-783

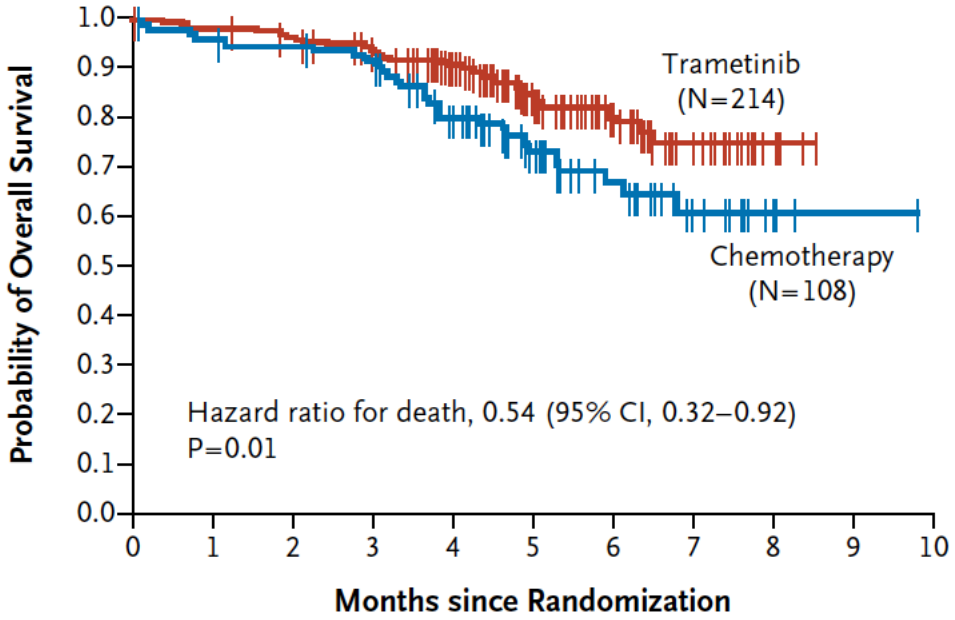
Available Immune Checkpoint Inhibitors

Drug	Mechanism
Ipilimumab	Anti–CTLA-4
Nivolumab	Anti–PD-1
Pembrolizumab	
Cemiplimab-rwlc	
Atezolizumab	Anti–PD-L1
Avelumab	
Durvalumab	

Immune checkpoint inhibitors to treat cancer. American Cancer Society: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/immune-checkpoint-inhibitors.html. Updated October 1, 2018. Accessed February 2019.

Metastatic Melanoma – Overall Survival

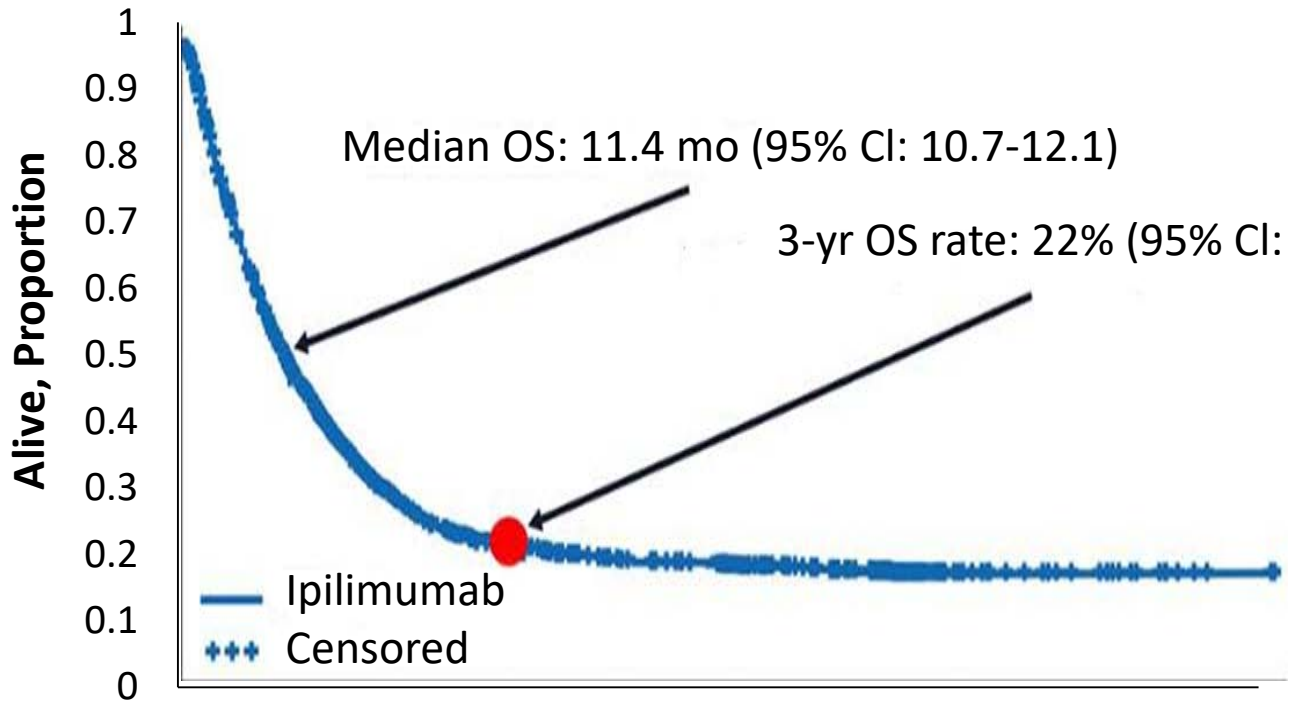
Chemotherapy



No. at Risk

Chemotherapy	108	96	94	90	72	47	28	15	4	1	0
Trametinib	214	208	203	192	170	105	53	24	5	0	0

Ipilimumab

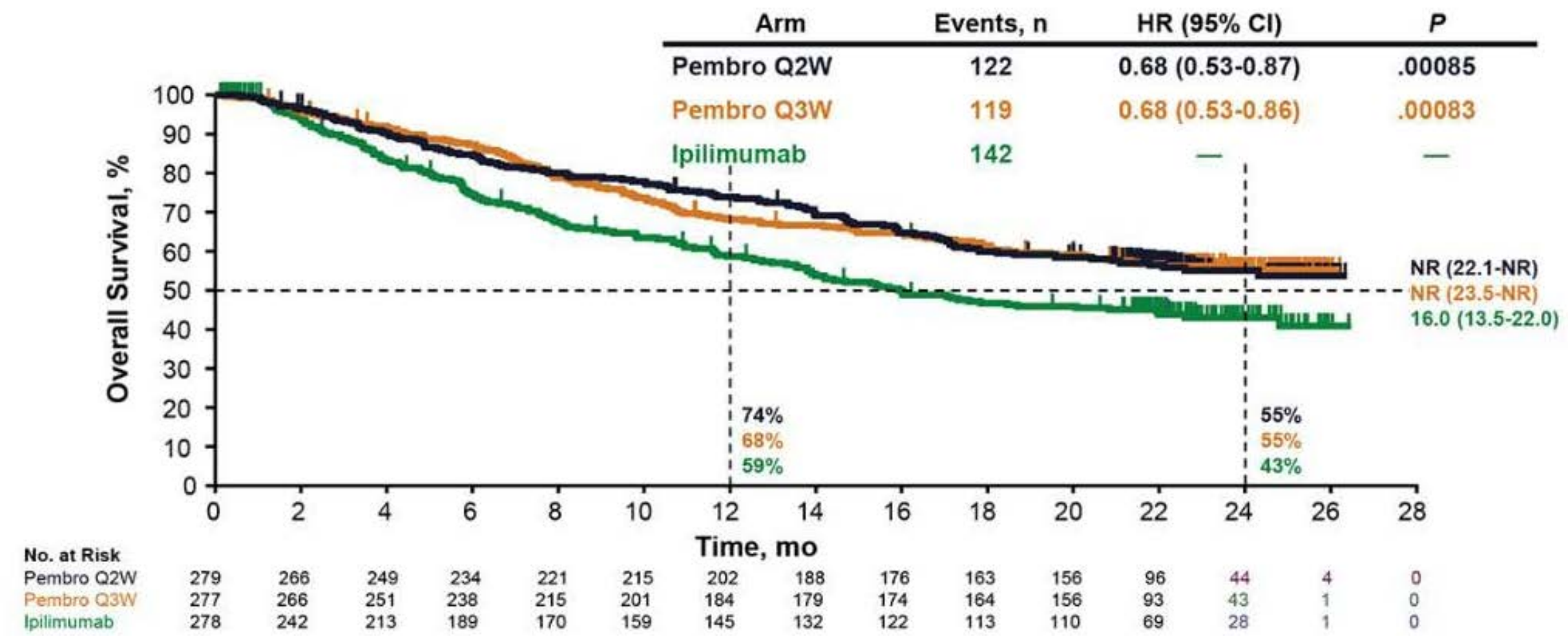


No. at Risk

Ipilimumab	1861	839	370	254	192	170	120	26	15	5	0

Schadendorf D, Hodi FS, Robert C, et al. *J Clin Oncol*. 2015;33(17):1889-94.

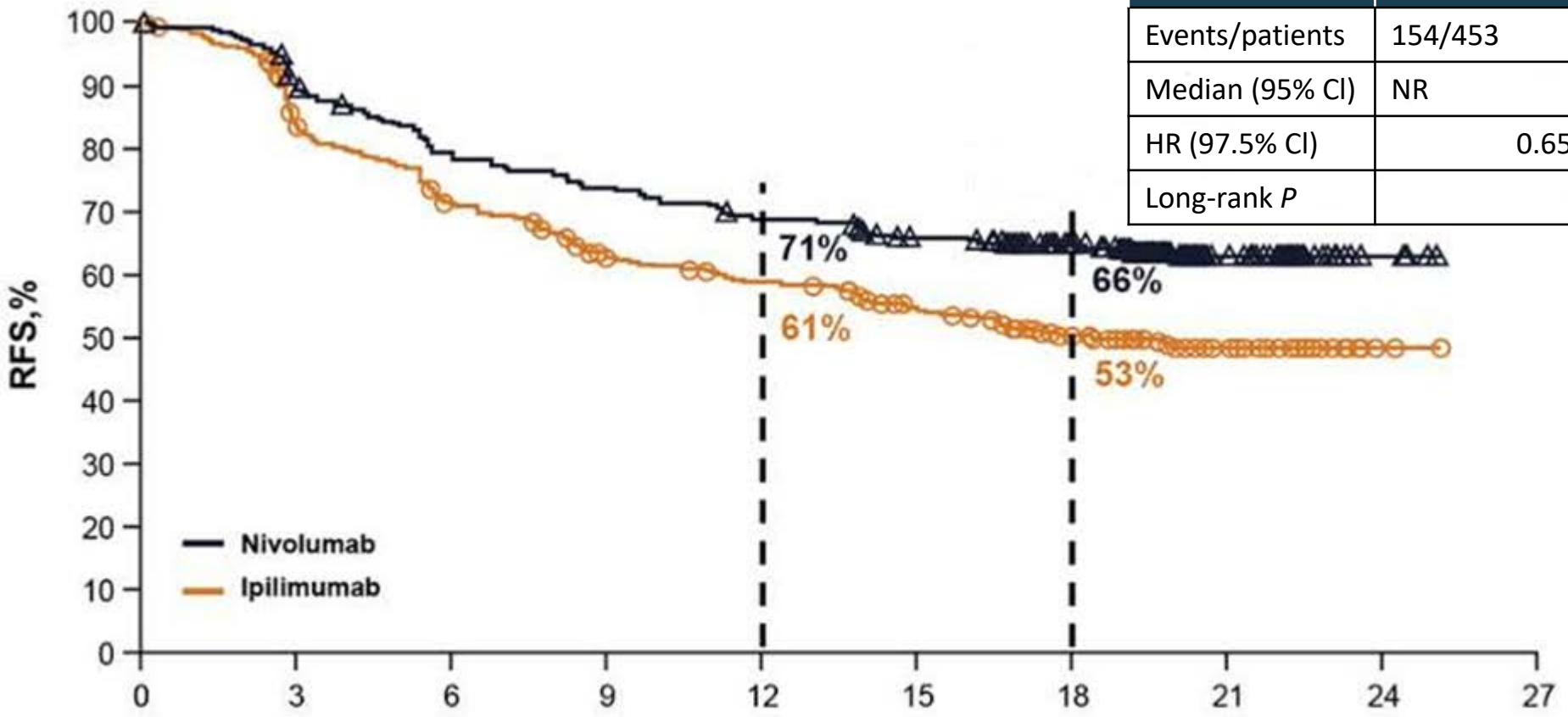
Pembrolizumab vs. Ipilimumab in Advanced Melanoma: Keynote-006



Schachter J, Ribas A, Long GV, et al. *J. Clin. Oncol*. 2016;34 (15) Suppl Abstr 9504.

Nivolumab vs. Ipilimumab in Resected Stage III/IV Melanoma: CheckMate-238

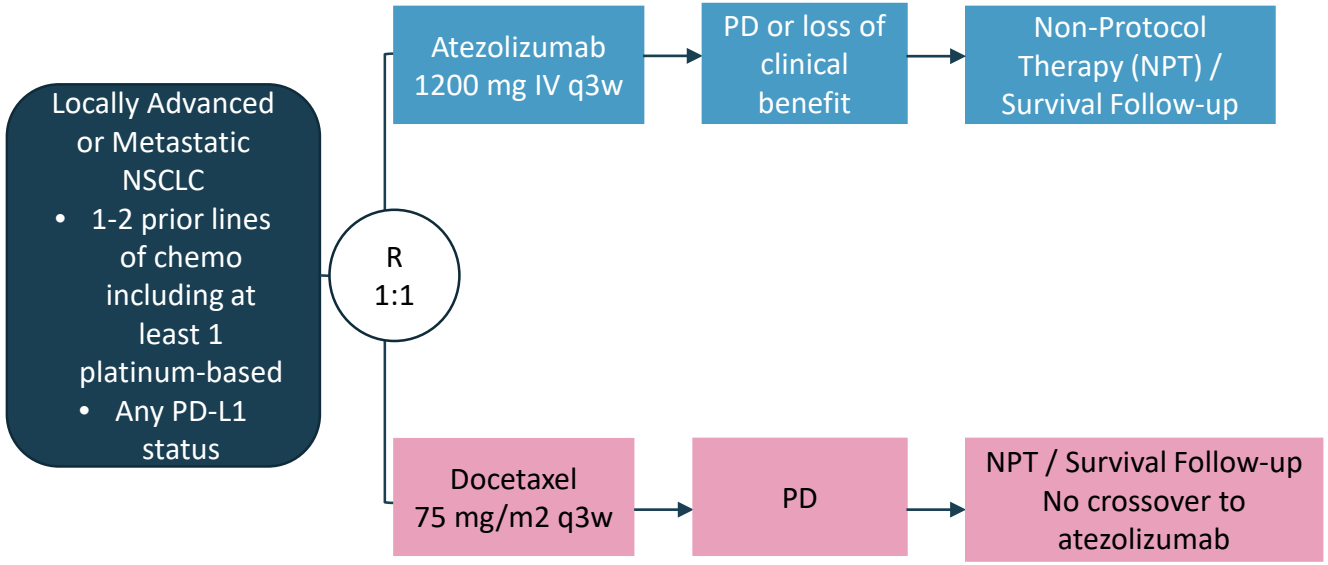
	Nivolumab	Ipilimumab
Events/patients	154/453	206/453
Median (95% CI)	NR	NR (16.6, NR)
HR (97.5% CI)	0.65 (0.51, 0.83)	
Long-rank *P*	<.0001	

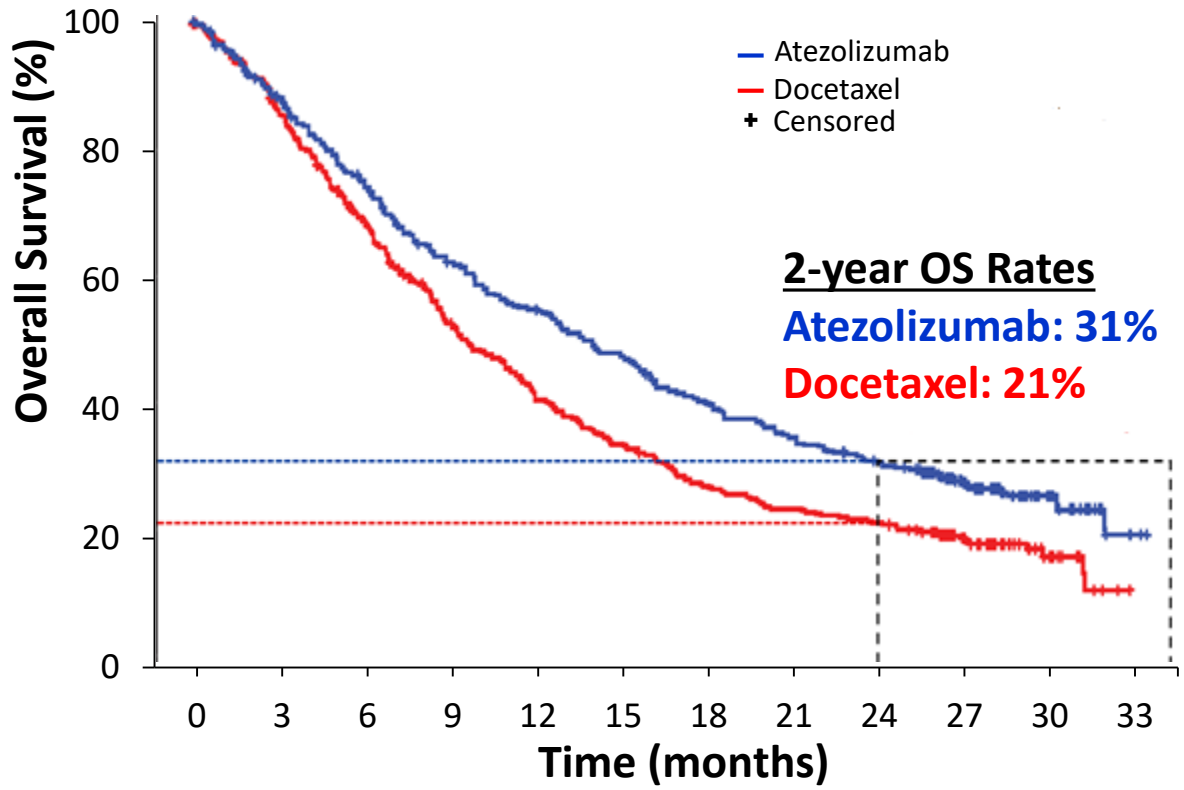


No. at Risk										
Nivolumab	453	399	353	332	311	291	249	71	5	0
Ipilimumab	453	364	314	209	252	225	184	56	2	0

Weber J, Mandala M, Del vecchio M, et al. *N Engl J Med*. 2017;377:1824-1835.

Long Term Survival at 2 years in OAK Trial: Atezolizumab vs Docetaxel in 2nd line+ NSCLC





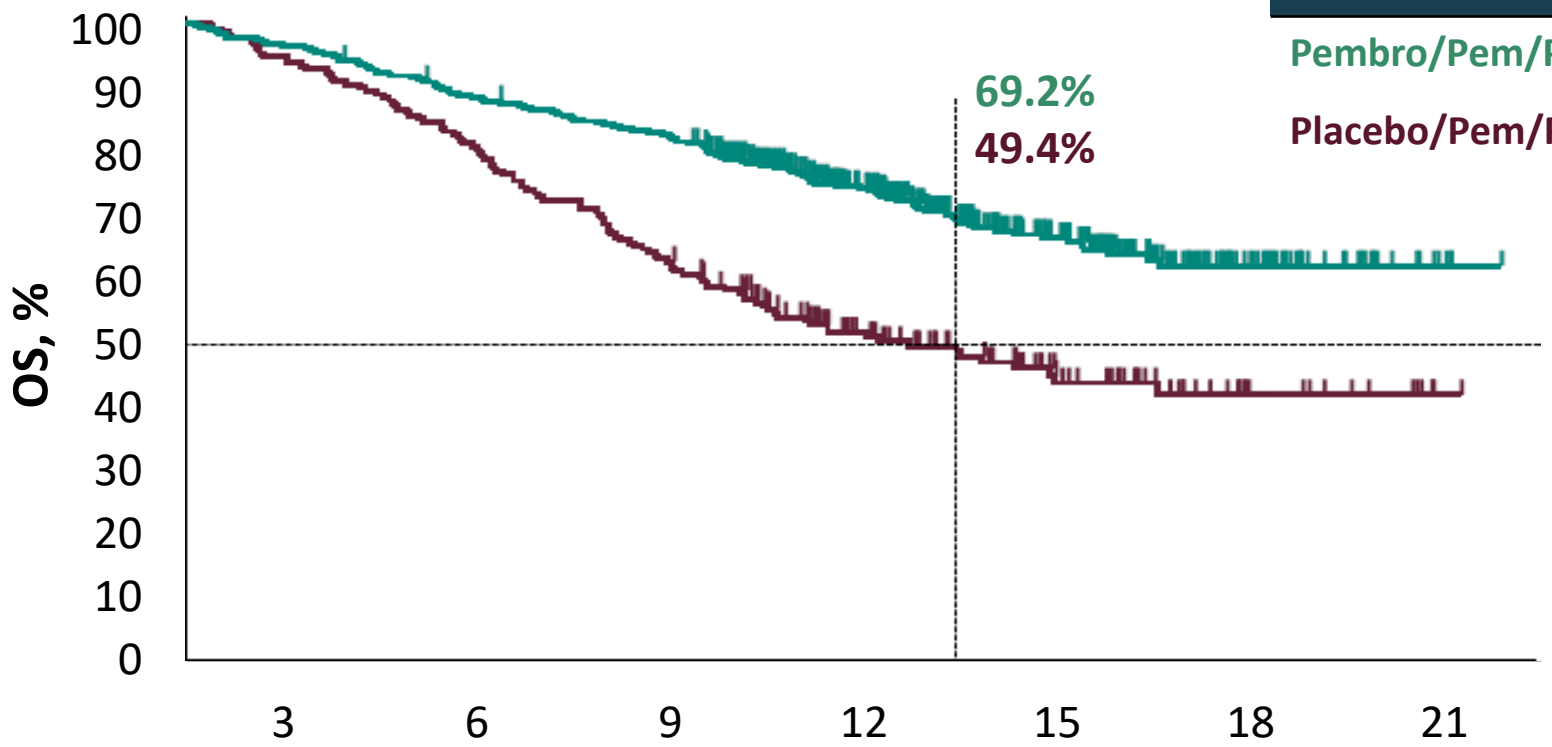
No. of Patients at Risk

Atezolizumab	425	363	305	248	218	188	157	136	119	71	27	2
Docetaxel	425	336	263	195	151	123	98	85	77	43	13	

Satouchi, et al. WCLC 2017

Phase 3 Trial of Chemo + Pembrolizumab or Chemo Alone for Previously Untreated NSCLC: Keynote-189

Overall Survival, ITT



	Events	HR (95% CI)	*P*
Pembro/Pem/Plat	31.0%	0.49	<0.00001
Placebo/Pem/Plat	52.4%	(0.38-0.64)	

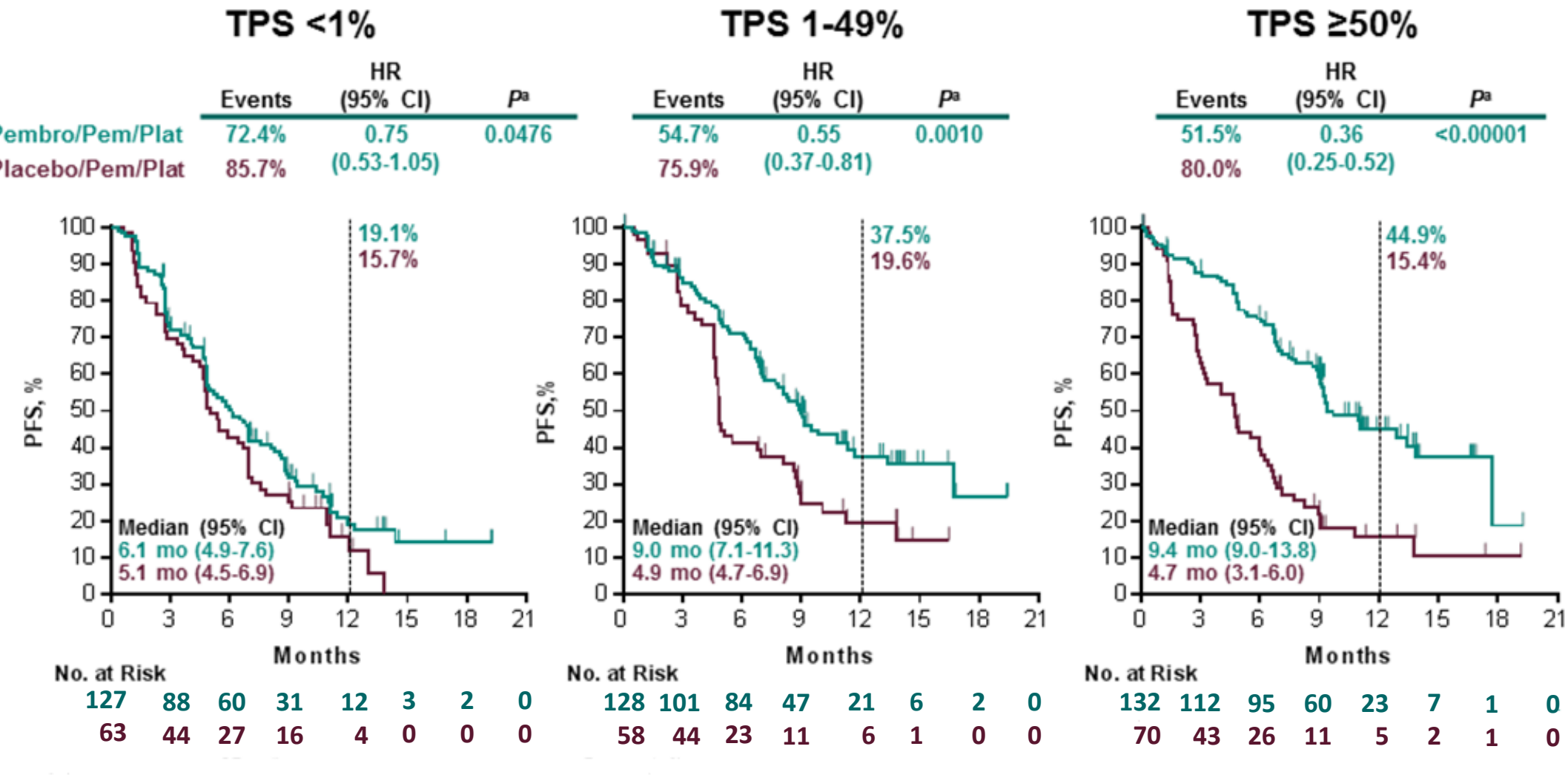
Median (96% CI)
NR (NE-NE)
11.3 mo (8.7-15.1)

No. at Risk							
410	377	347	278	163	71	18	0
206	183	149	104	59	25	8	0

Data cutoff date: Nov 8, 2017

Gandhi L, Rodríguez-Abreu D, Gadgeel S, et al. Paper presented at: American Association for Cancer Research Annual Meeting; April 14-18, 2018; Chicago, IL.

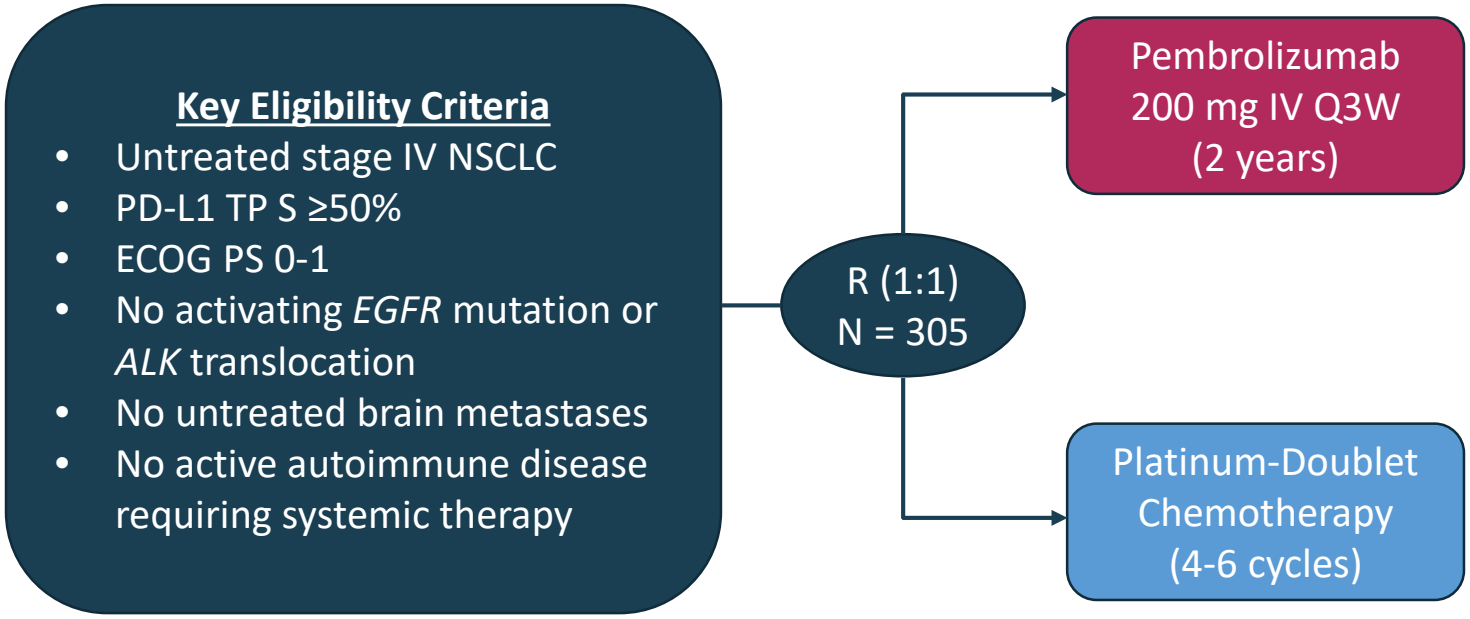
PD-L1 TPS Predicts PFS: Keynote-189



Gandhi L, Rodríguez-Abreu D, Gadgeel S, et al. Paper presented at: American Association for Cancer Research Annual Meeting; April 14-18, 2018; Chicago, IL.

Pembrolizumab vs Chemo in 1st Line NSCLC

KEYNOTE-024 Study Design (NCT02142738)



Key End Points

Primary: PFS (RECIST v1.1 per blinded, independent central review)

Secondary: OS, ORR, safety

Exploratory: DOR

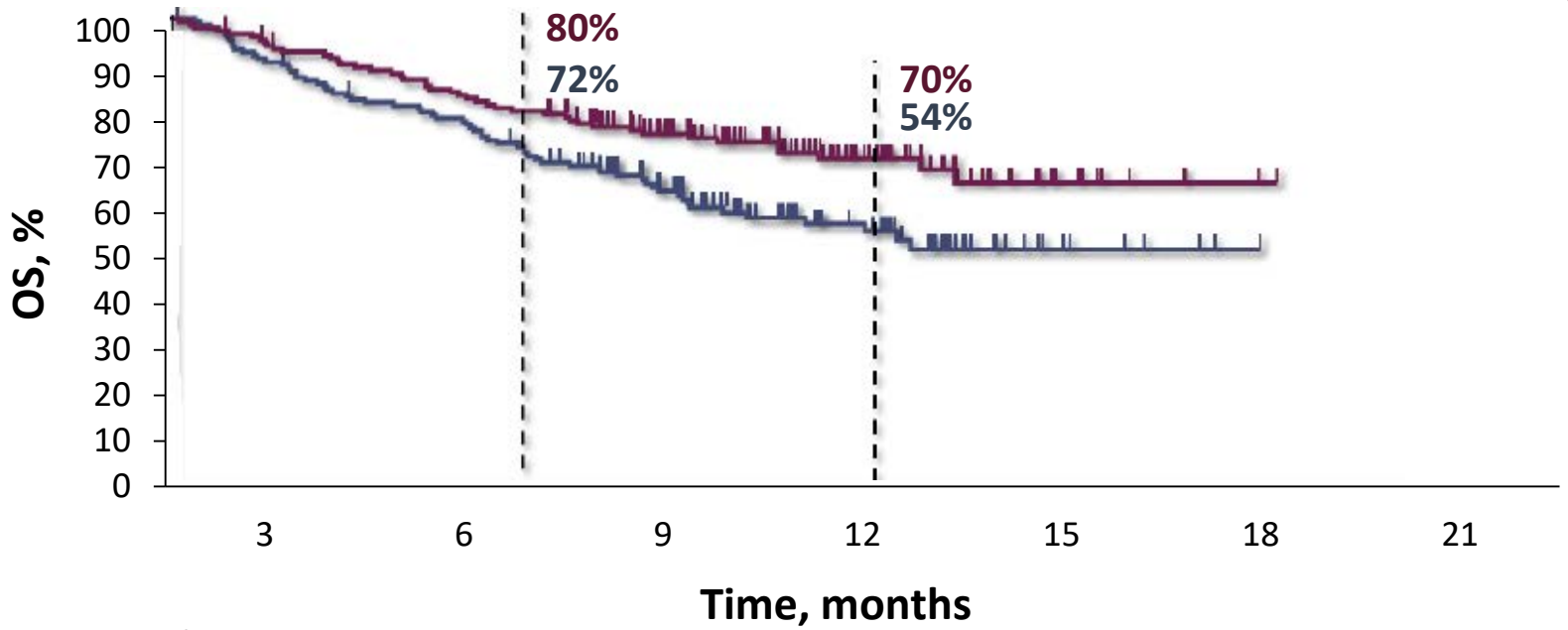
- Carbo + pemetrexed*
- Cis + pemetrexed*
- Carbo + gemcitabine
- Cis + gemcitabine
- Carbo + paclitaxel

Reck, et al; NEJM 2016

Pembrolizumab vs Chemo in 1st Line NSCLC

Overall Survival

	Events, n	Median, mo	HR (95% CI)	P
Pembro	44	NR	0.60 (0.41-0.89)	0.005
Chemo	64	NR		



No. at risk

154	136	121	82	39	11	2	0
151	123	106	64	34	7	1	0

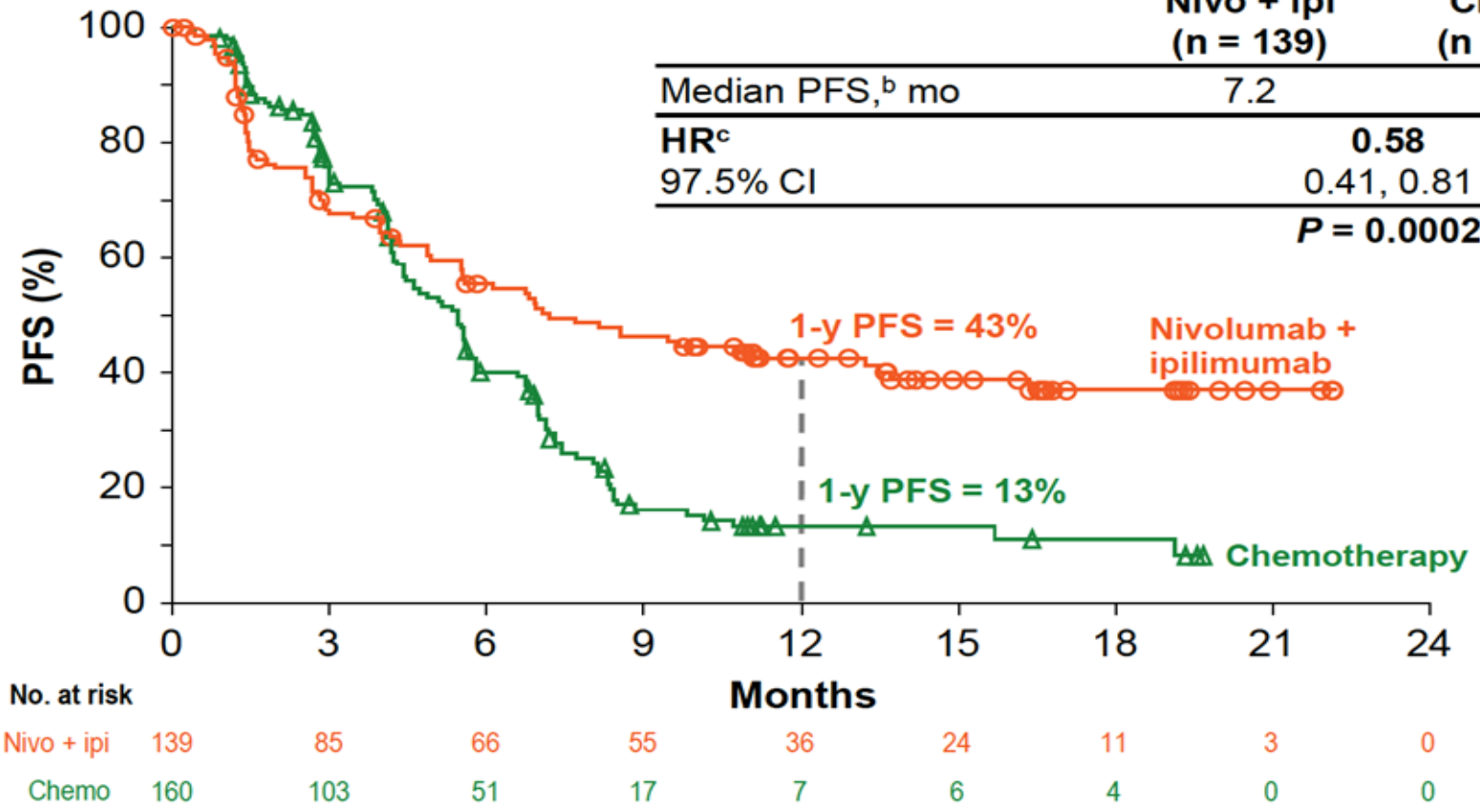
Reck, et al; NEJM 2016

Data cut-off: May 9, 2016

CheckMate 227: Nivo + Ipi in 1L NSCLC With High TMB (≥10 mut/Mb)

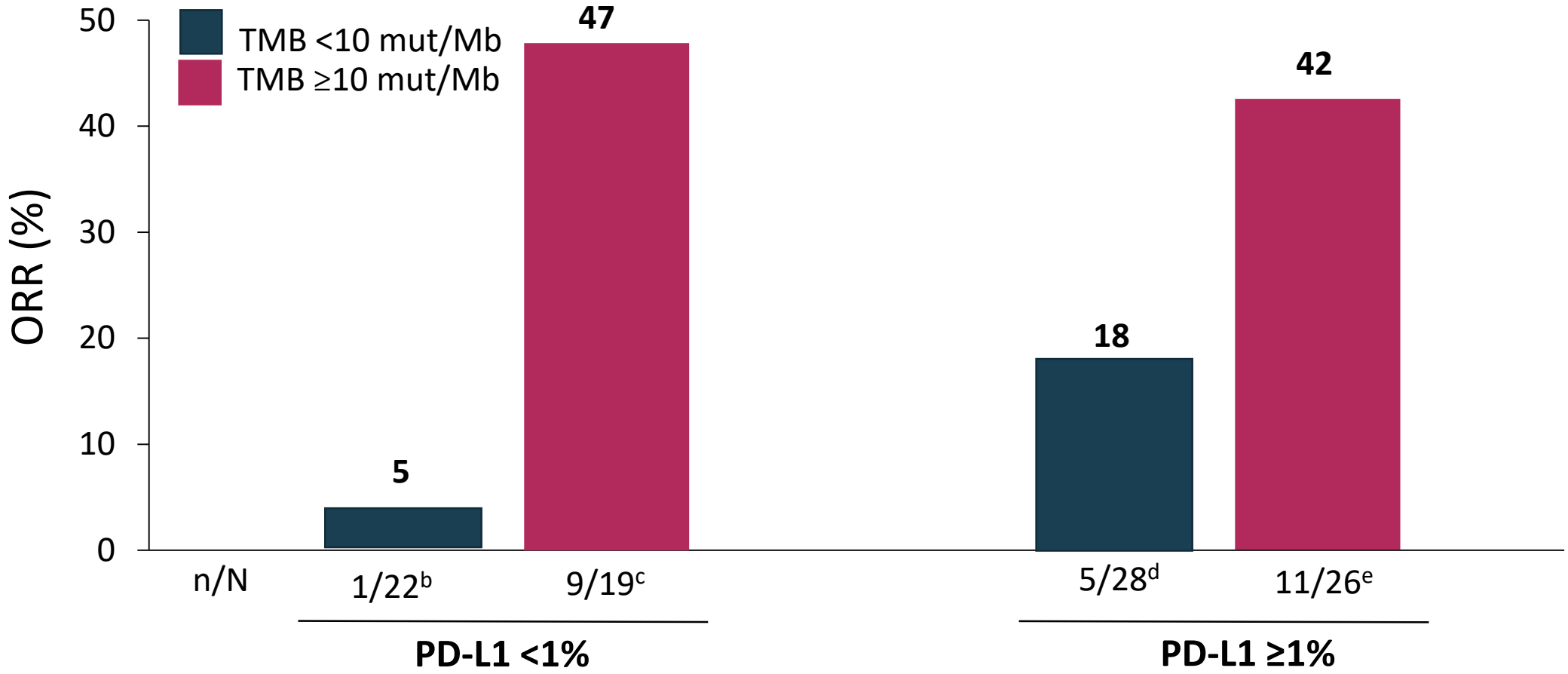
Co-primary Endpoint: PFS With Nivolumab + Ipilimumab vs Chemotherapy in Patients With High TMB (≥10 mut/Mb)[a]

	Nivo + ipi (n = 139)	Chemo (n = 160)
Median PFS,[b] mo	7.2	5.4
HR[c]	**0.58**	
97.5% CI	0.41, 0.81	
	***P* = 0.0002**	



- In patients with TMB <10 mut/Mb treated with nivo + ipi vs chemo, the HR was 1.07 (95% CI: 0.84, 1.35)[d]

Responses Observed in TMB ≥10 mut/Mb Regardless of Tumor PD-L1 Expression



[a]ORR for all treated patients: 41% in PD-L1 ≥1% subgroup (n=138) and 15% in PD-L1 <1% subgroup 114; [b]CR=0; [c]CR=16%; [d]CR=4%; [e]CR=4%

Ramalingam S, Hellmann MD, Awad M, et al. Presented at: AACR Annual Meeting 2018; April 14-18, 2018; Chicago, Illinois. Abstract CT078

Predicting Response: Neoantigens and Related Biomarkers

- Neoantigens
  - Tumors with a high burden of neoantigens have been shown to be more sensitive to immunotherapy
  - Being investigated in anti-CTLA-4 and anti-PD-1 therapy
- Tumor Mutational Burden (TMB)
  - May potentially be used as a surrogate to indirectly assess neoantigen load
- Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) status
  - May potentially be used as a surrogate to indirectly assess neoantigen load
- Tumor Microenvironment

Schumacher TN, Schreiber RD. *Science*. 2015;348(6230):69-74.
Eggermont LJ, Paulis LE, Tel J, Figdor CG. *Trends Biotechnol*. 2014;32(9):456-65.

Predicting response to Checkpoint inhibitors Tumor microenvironment and the Inflamed Phenotype

"Hot" or "inflamed" tumors due to immune recognition

- High infiltration of CD8+ Tumor Infiltrating Lymphocytes (TILs)
- Presence of chemokines
- Type 1 interferon
- Melanoma and other tumor types

Predicting response to Checkpoint inhibitors Tumor microenvironment

Compliment System

Lag-3

Single Cell Characterization of the Immunological Microenvironment

MA11.06 - Prognostic Value of Complement System in NSCLC and its Association with PD-1 and PD-L1 Expression (Now Available)

11:05 - 11:10 | Presenting Author(s): Luis M Montuenga | Author(s): Daniel Ajona, María José Pajares, Javier Freire, Javier Gomez-Roman, Elena Martinez-Terroba, Sergio Ortiz-Espinosa, Ana Lledo, Elisabeth Arenas-Lazaro, Jackeline Agorreta, Fernando Lecanda, Ruben Pio

MA11.07 - Expression of LAG-3 and NY-ESO-1 In Tumor Cells is Promising Biomarker Predicting Durable Clinical Benefit of PD-1 Blockade in Advanced NSCLC (Now Available)

11:10 - 11:15 | Presenting Author(s): Hee Ryeong Jang | Author(s): Se Hyun Kim, Kyoung Jin Suh, Yu Jung Kim, Mi So Kim, Bhumsuk Keam, Tae Min Kim, Jin-Haeng Chung, Dong-Wan Kim, Dae Seog Heo, Jong-Seok Lee

MA11.08 - Discussant - MA 11.05, MA 11.06, MA 11.07 (Now Available)

11:15 - 11:30 | Presenting Author(s): Erin Schenk

MA11.09 - Single-Cell Characterization of the Immunologic Microenvironment in Advanced-Stage, Oncogene-Driven NSCLC (Now Available)

11:30 - 11:35 | Presenting Author(s): Julia Rotow | Author(s): Caroline McCoach, Ashley Maynard, David Naeger, Yaron Gesthalter, K Pallav Kolli, Spyros Darmanis, Trever G Bivona, Collin Blakely, Jonathan Weissman

MA11.10 - Identification of Mismatch Repair Deficient Lung Adenocarcinomas Using Targeted Next-Generation Sequencing (Now Available)

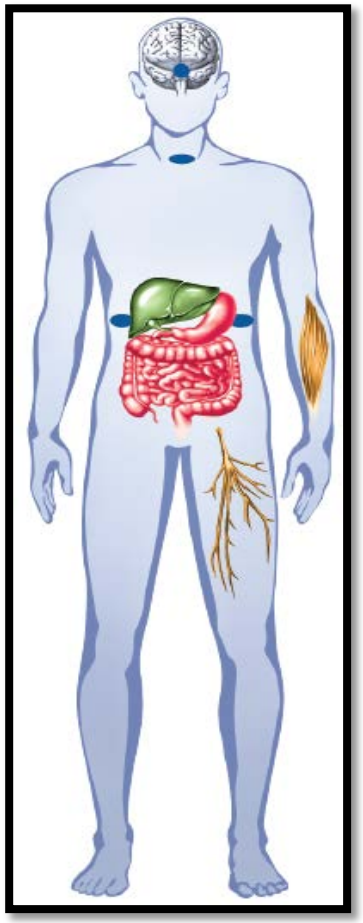
11:35 - 11:40 | Presenting Author(s): Navin Rajput Mahadevan | Author(s): Priyanka Shivadasani, Jonathan Nowak, Mark

World Lung Conference, 2018

Immune-Related Adverse Events (IRAEs)

Activation of the immune system against tumors can result in a novel spectrum of IRAEs

- May be due to cytokine release by activated T cells
- May be unfamiliar to clinicians
- Requires a multidisciplinary approach
- Can be serious
- Requires prompt recognition and treatment
- Requires patient and HCP education



Occasional (5%-20%) IRAEs
Grade 3/4 Uncommon

- Hypophysitis
- Thyroiditis
- Adrenal insufficiency
- Colitis
- Dermatitis
  - Macropapular/pruritus
- Pneumonitis
- Hepatitis
- Pancreatitis
- Arthritis
- Neuropathies

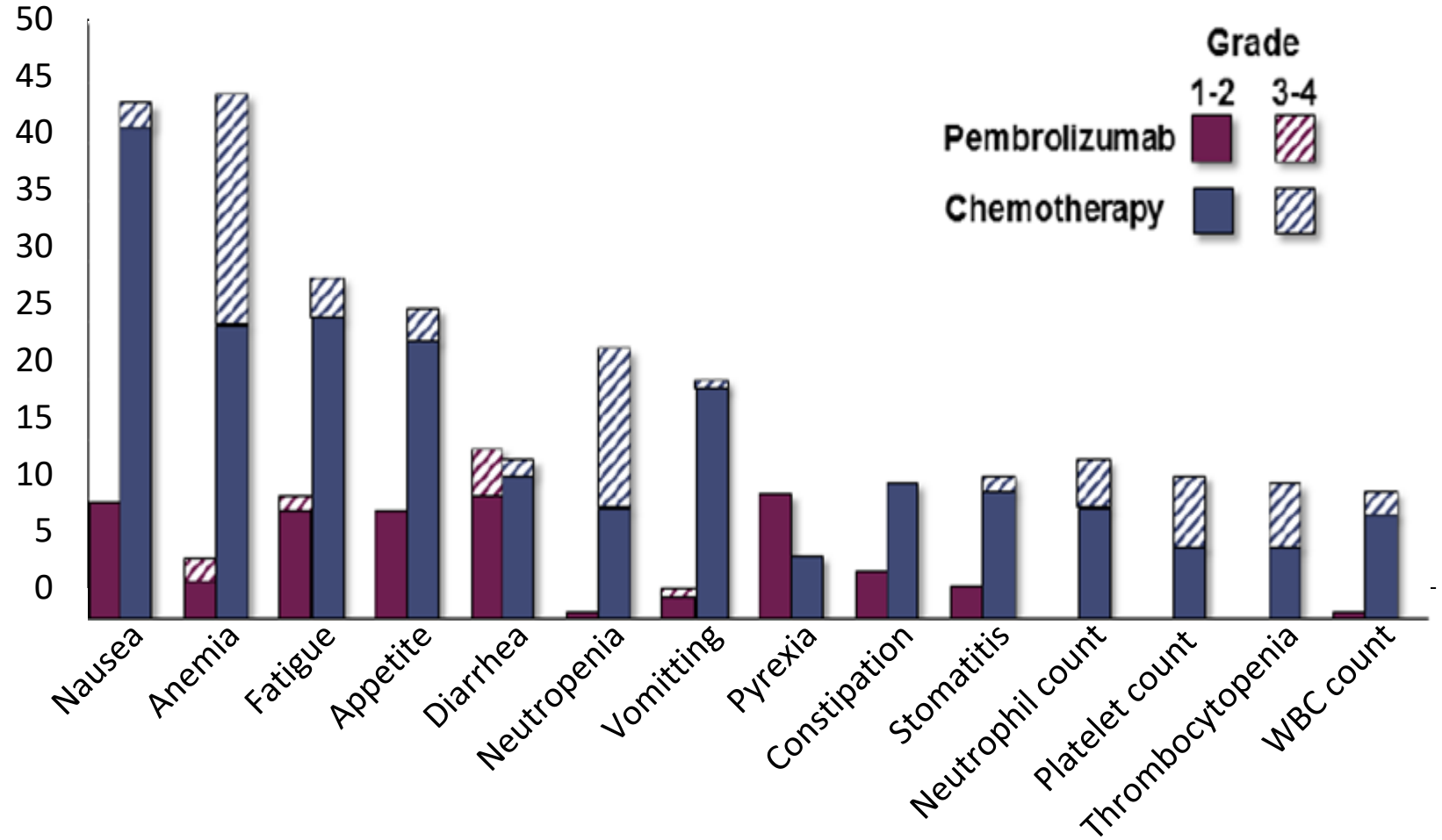
Amos SM, Duong CP, Westwood JA, et al. Blood. 2011;118(3):499-509.
YERVOY immune-related adverse reactions management guide. October 2012.
Available at https://www.yervoy.co.uk/Images/6682_IrAR%20management%20guide%20731EMEA12PM014.pdf. Accessed September 2014;
Chin K, Ibrahim R, Berman D, et al. *Ann Oncol* 2008;19 Suppl 8: viii239–viii246. Abstr 787P.

Safety and Tolerability of Therapy with Checkpoint Inhibitors

- Spectrum of observed toxicities:
  - GI: diarrhea and colitis
  - Pulmonary: pneumonitis (challenges in diagnosis)
  - Dermatologic: rash and pruritus
  - Hepatic toxicity (importance of plasma screening)
  - Endocrine: hypophysitis, hypothyroidism (importance of plasma screening)
- Timing for appearance of toxicities
- Fraction of patients with toxicities: Anti-PD-1 versus combined anti-PD-1 and anti-CTLA-4

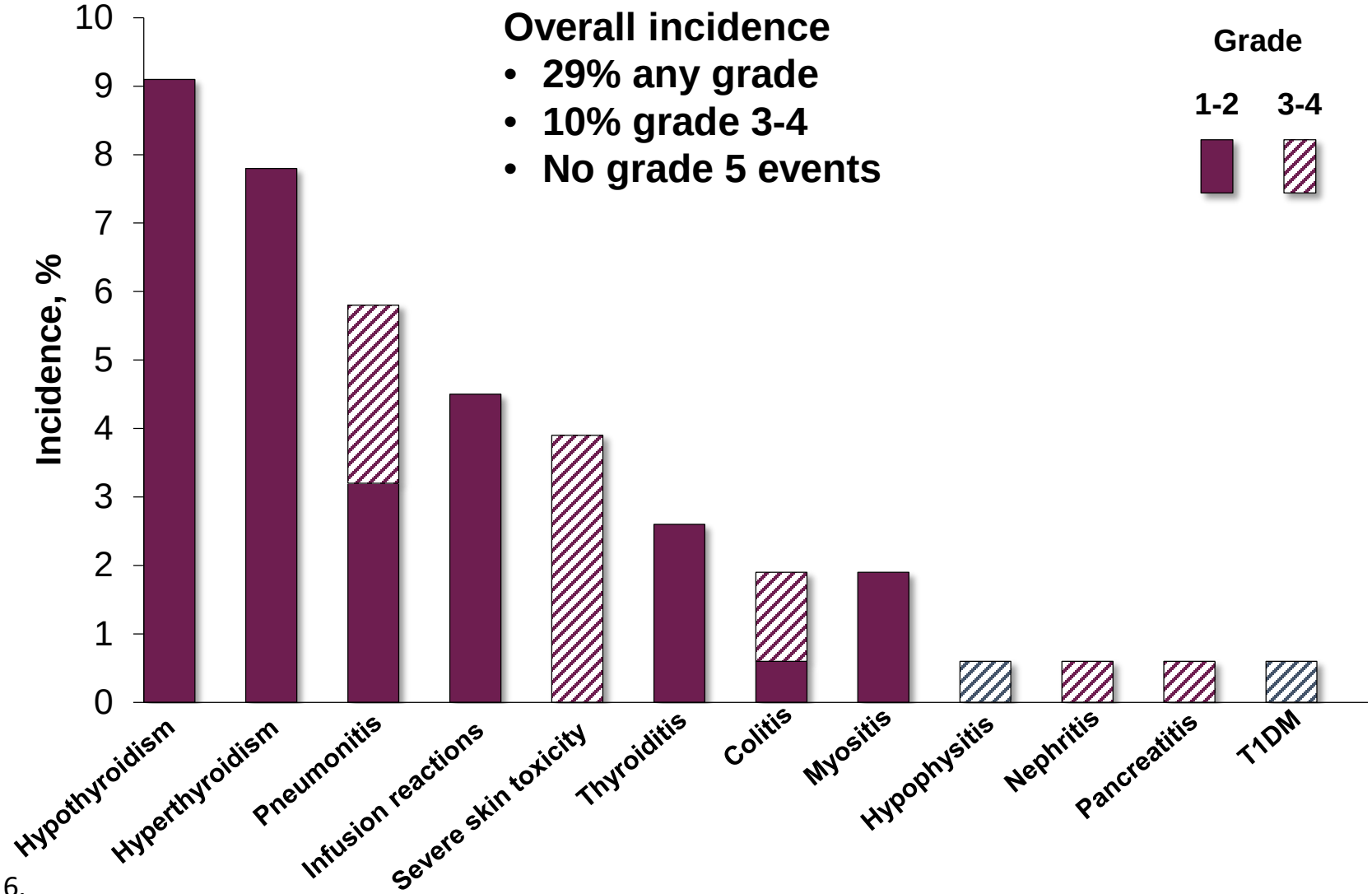
Pembrolizumab vs Chemo in 1st Line NSCLC

Treatment-Related AEs With Incidence >10%



Reck, et al; NEJM 2016

Immune-Mediated AEs With Pembrolizumab



Data cut-off: May 9, 2016.

All Providers Must Be Vigilant in Recognizing Diverse Toxicities

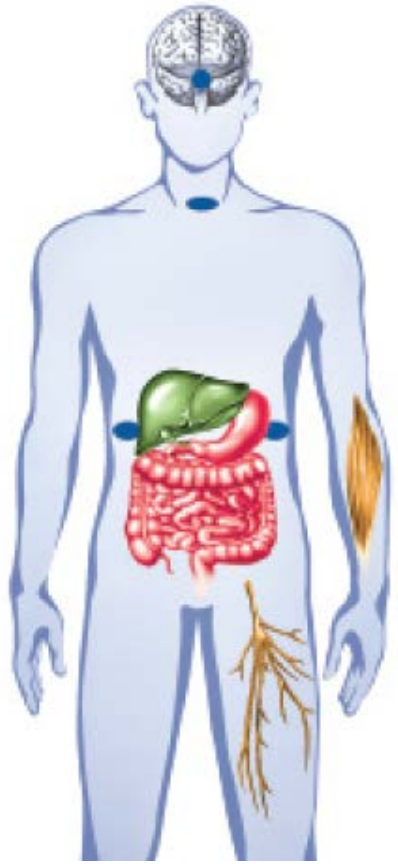
Hypophysitis

Thyroiditis

Adrenal insufficiency

Colitis

Dermatitis



Pneumonitis

Hepatitis

Pancreatitis

Motor & sensory neuropathies

Arthritis

- Less common: hematologic; cardiovascular; ocular, renal

Lipson, ASCO 2014

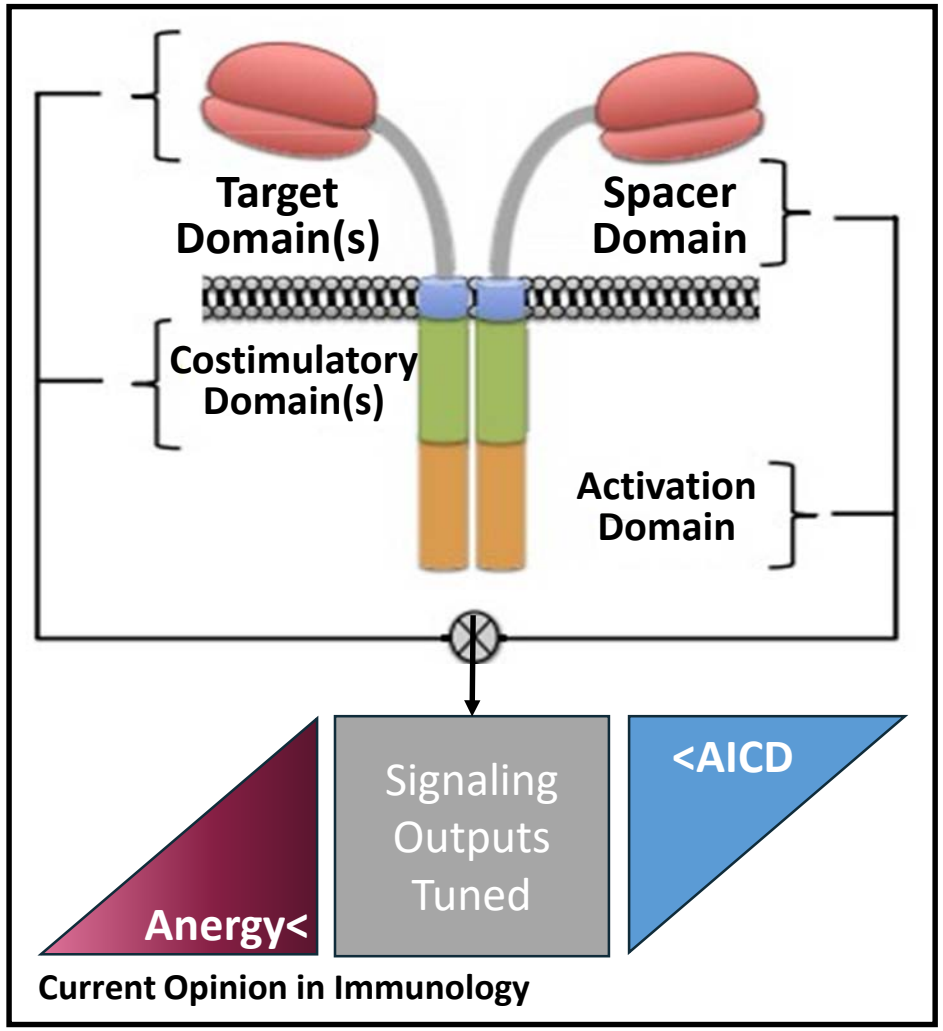
IRAEs May Require Weeks of High Dose Steroids and Complex Management

Grade	Management Options
Grade 1	• Supportive care +/- hold drug
Grade 2	• Hold drug • Re-dose at lower dose once toxicity resolved to </= Grade 1 • Low dose steroids if symptoms do not resolve in 1 week
Grade 3/4	• D/C drug • R/o other etiologies • Consider empiric antibiotics, biopsy • High dose steroids • Taper over >/= 1 month until toxicity resolves to </= Grade 1

Even Low Grade IRAEs Cannot Be Ignored

Grade	Management Options
Grade 1	• Supportive care +/- hold drug
Grade 2	• Hold drug • Re-dose at lower dose once toxicity resolved to </= Grade 1 • Low dose steroids if symptoms do not resolve in 1 week
Grade 3/4	• D/C drug • R/o other etiologies • Consider empiric antibiotics, biopsy • High dose steroids • Taper over >/= 1 month until toxicity resolves to </= Grade 1

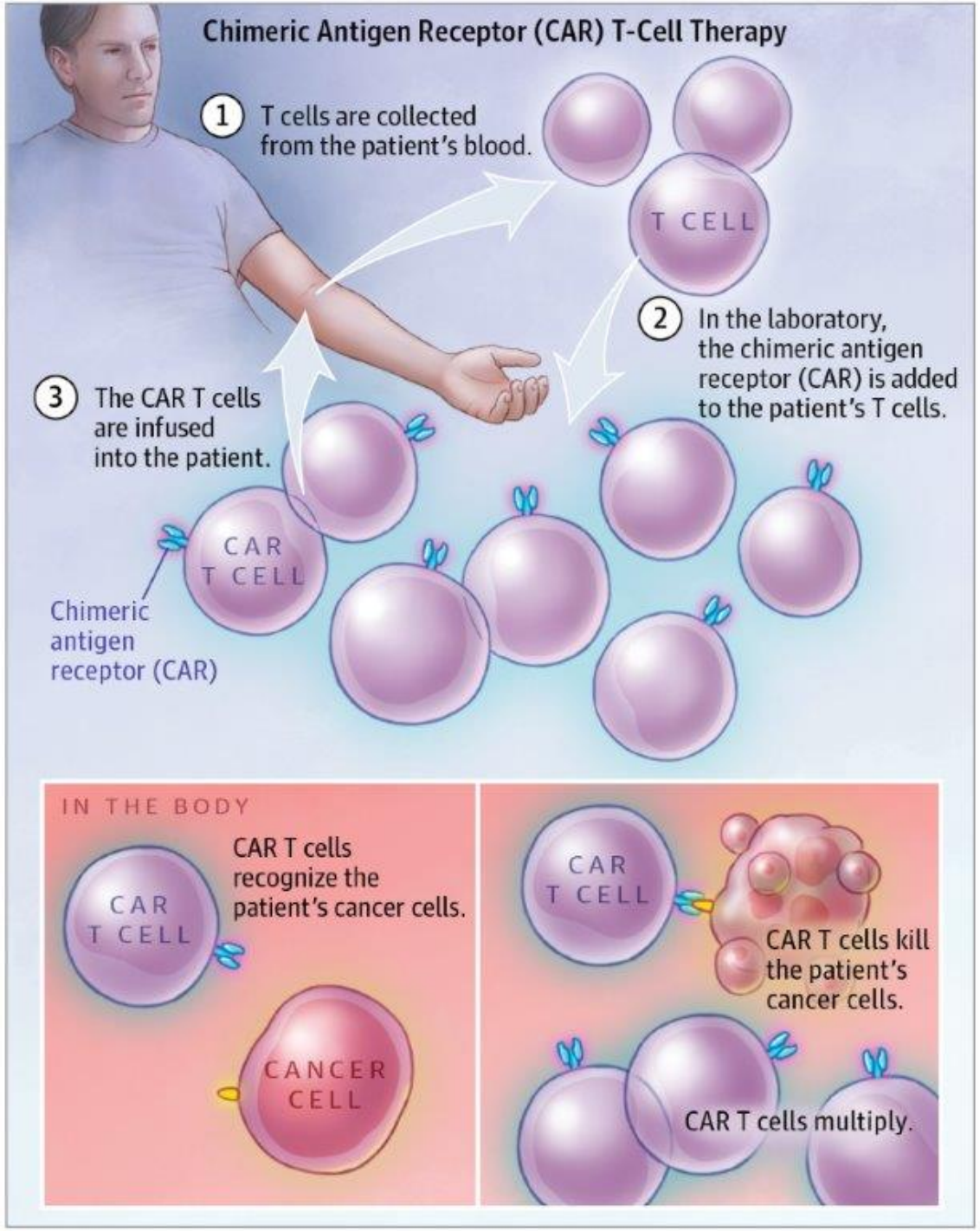
Chimeric antigen receptor T-cell (CAR-T) Therapy



Chimeric antigen receptors (CARs) are fusion molecules typically composed of the following:

- An extracellular single chain variable fragment (scFv) of a monoclonal antibody (mAb) specific for a surface molecule on the tumor cell
- A spacer domain that provides flexibility and optimizes T cell and target cell engagement
- A transmembrane domain
- Signaling modules that trigger T cell effector functions

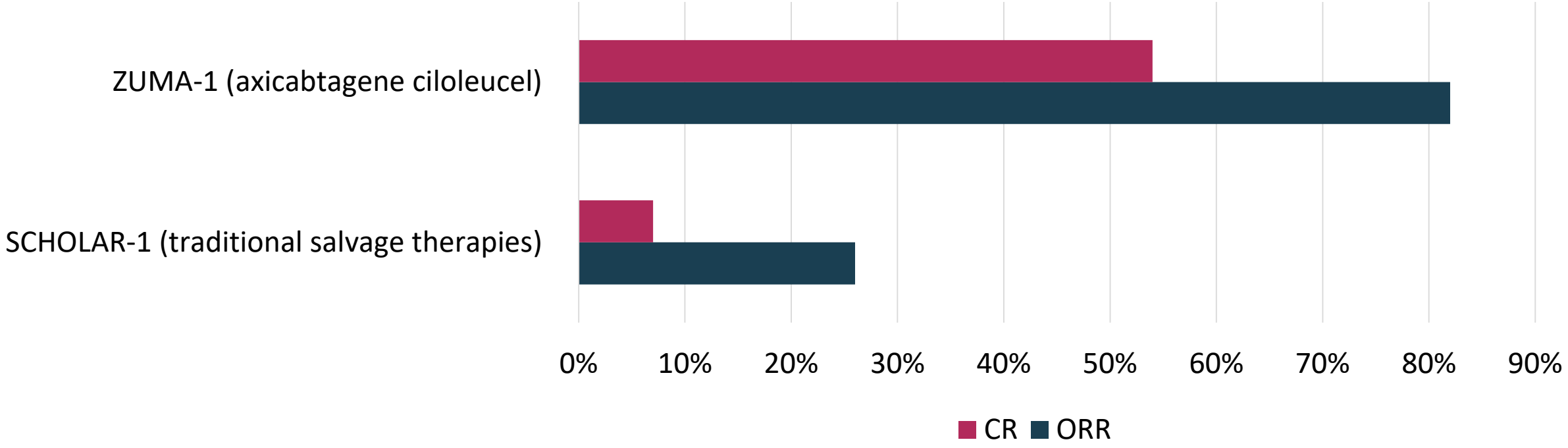
Jensen MC, Riddell SR. *Curr Opin Immunol.* 2015;33:9-15.



Pagel & West, JAMA Onc, 11/2017

Axicabtagene Ciloleucel in Refractory Aggressive Non-Hodgkin Lymphoma (NHL)

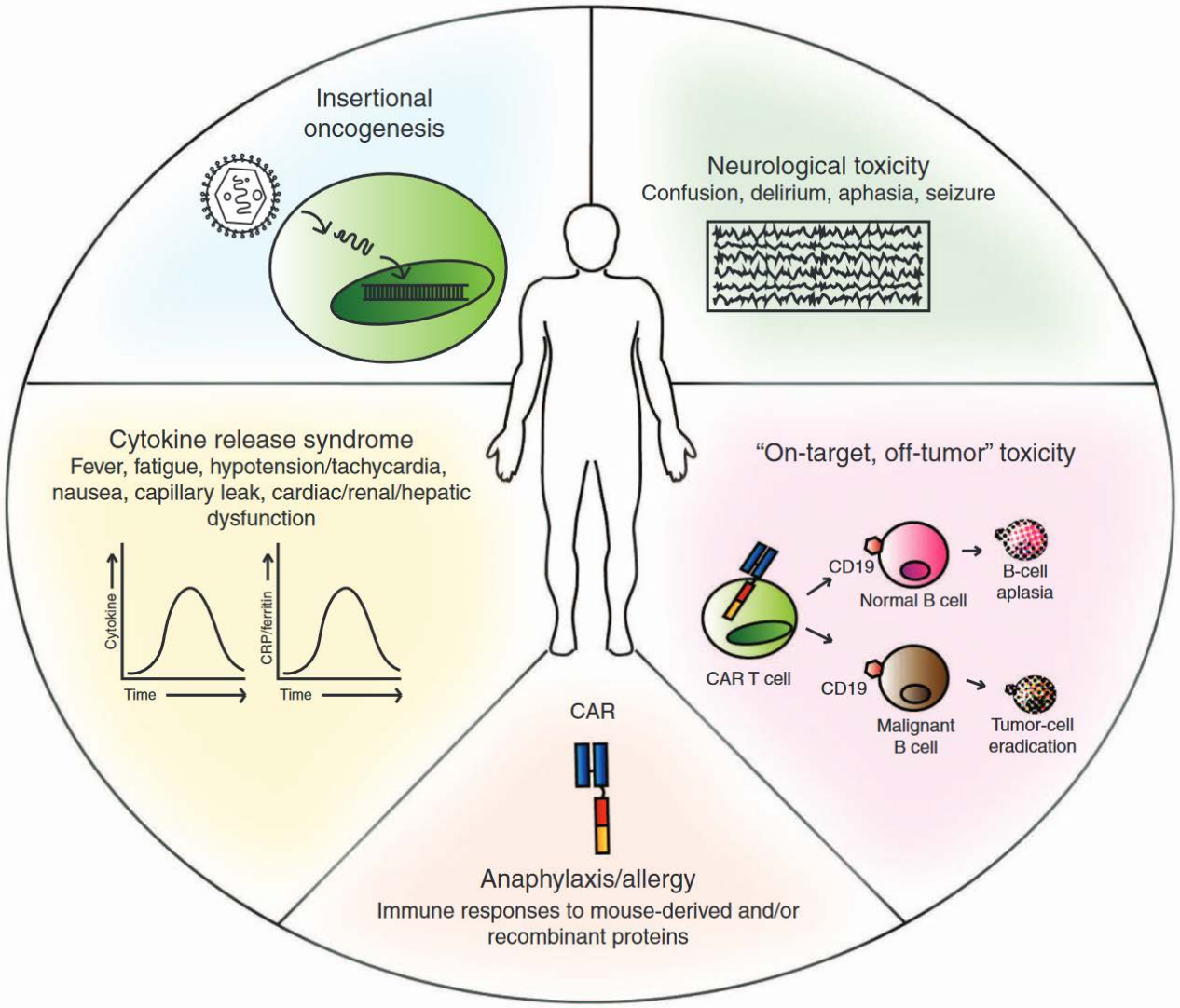
Complete Response (CR) and Objective Response Rate (ORR) Compared with Traditional Salvage Therapies



Crump M, Neelapu SS, Farooq U, et al. *Blood*. 2017;130(16):1800-1808.
Locke FL, Neelapu SS, Bartlett NL, et al. *Cancer Res*. 2017;77(13) Suppl Abstract CT019.

Toxicity of CAR-T Cells

- Neurologic toxicity: confusion, delirium, aphasia, seizures
- Anaphylaxis
- Cytokine release syndrome



Bonifant CL, Jackson HJ, Brentjens RJ, Curran KJ.
Mol Ther Oncolytics. 2016;3:16011.

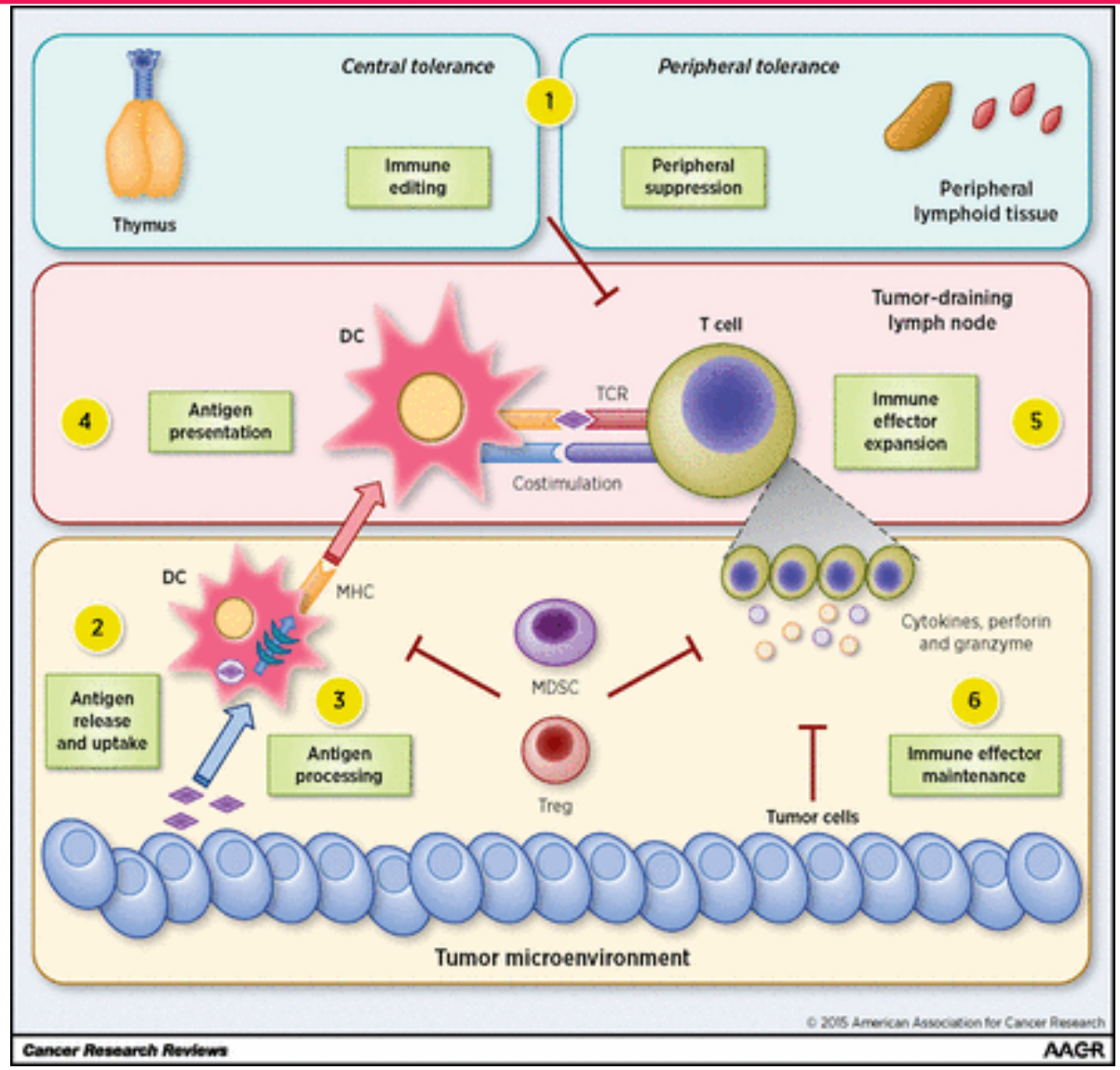
Characterizing the Manifestations of Cytokine Release Syndrome (CRS) Across Various Organ Systems

Organ system	Symptoms
Constitutional	Fever ± rigors, malaise, fatigue, anorexia, myalgias, arthralgias, nausea, vomiting, headache
Skin	Rash
Gastrointestinal	Nausea, vomiting, diarrhea
Respiratory	Tachypnea, hypoxemia
Cardiovascular	Tachycardia, widened pulse pressure, hypotension, increased cardiac output (early), potentially diminished cardiac output (late)
Coagulation	Elevated D-dimer, hypofibrinogenemia ± bleeding
Renal	Azotemia
Hepatic	Transaminitis, hyperbilirubinemia
Neurologic	Headache, mental status changes, confusion, delirium, word finding difficulty or frank aphasia, hallucinations, tremor, dysmetria, altered gait, seizures

Lee DW, Gardner R, Porter DL, et al. *Blood*. 2014;124(2):188-95.

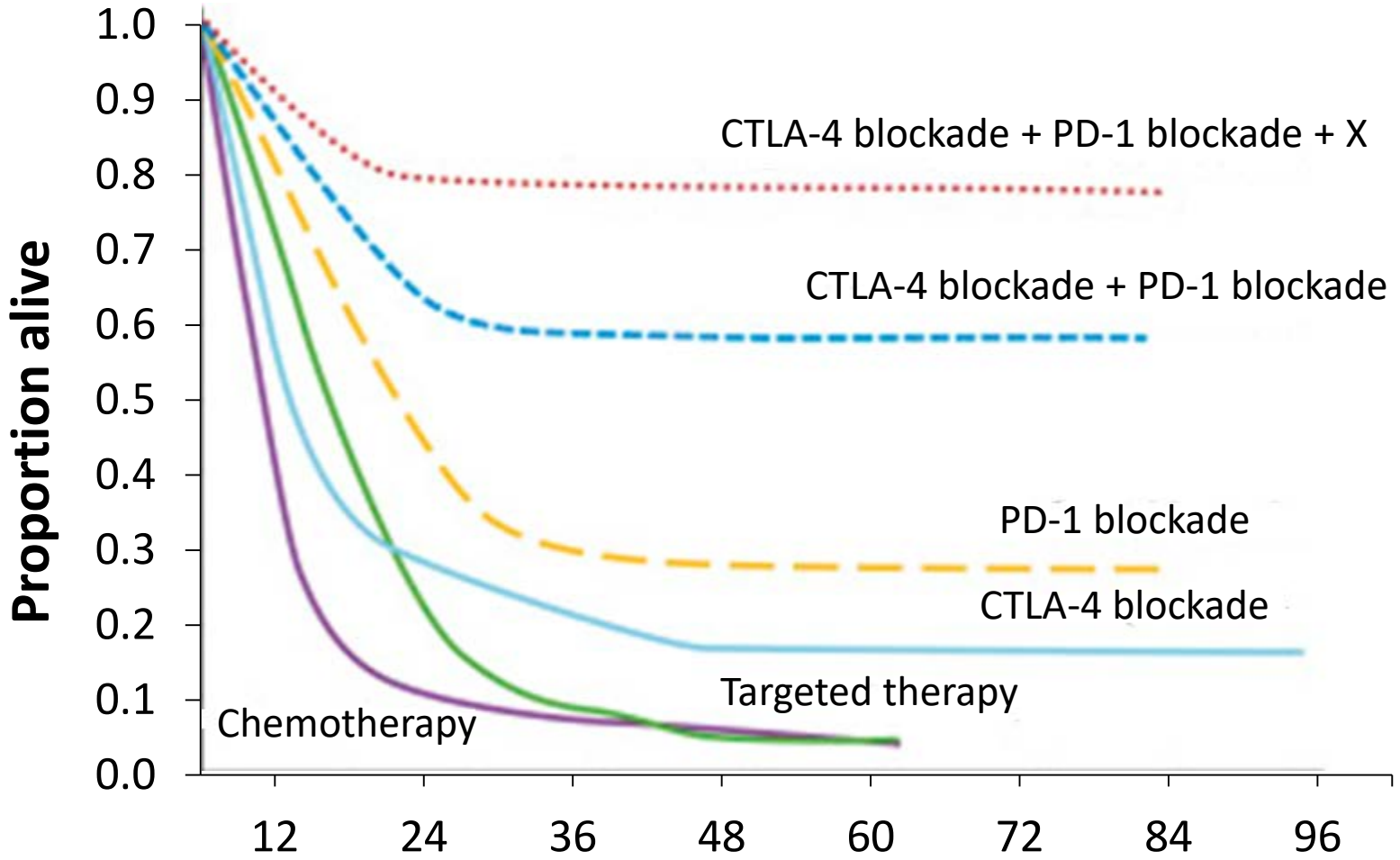
The Theory of Combination I-O Therapy

Multiple mechanisms that limit autoimmunity need to be overcome in cancer immunotherapy



Makkouk A, Weiner GJ. *Cancer Res.* 2015;75(1):5-10.

Future Promise in Combination I-O Therapy



Adapted from: Emens LA, Ascierto PA, Darcy PK, et al. *Eur J Cancer*. 2017;81:116-129.

Summary

- The immune system is capable of recognizing and eliminating tumor cells in the tumor microenvironment
- Immune balance is maintained through the combination of activating and inhibitory signaling pathways that modulate the activity of effector cells, such as cytotoxic T cells and NK cells
- Among the latest innovations in cancer therapies are immuno-oncology agents: these include checkpoint inhibitor antibodies aimed at CTLA-4 and PD-1/L1 and CAR-T therapies
- These agents have demonstrated promise in the treatment of several tumor types, with findings often characterized by extended OS in the long-term
- Activation of the immune system against tumors can result in a novel spectrum of IRAEs with checkpoint inhibitors and CARs/NEs with CAR-T therapies
- Combination regimens offer further potential for future regimens, with a number of biomarkers being assessed to predict response to specific I-O therapies

PD-1/L1 Antagonist Activity Across Tumor Types

Active

- Melanoma
- Renal cancer (clear cell)
- NSCLC – adenocarcinoma and squamous cell
- Head and neck cancer
- Urothelial (bladder) cancer
- Merkel Cell
- Mismatch repair deficient tumors
- Hodgkin Lymphoma
- Hepatocellular carcinoma
- Gastric and GE junction
- Cervical cancer
- PMBCL

Is the Cost Sustainable????

- Anal cancer
- Squamous Cell Ca of Skin
- Small cell lung cancer
- Triple negative breast cancer
- Ovarian cancer
- Thymic carcinoma
- Mesothelioma
- Diffuse large cell lymphoma
- Follicular lymphoma

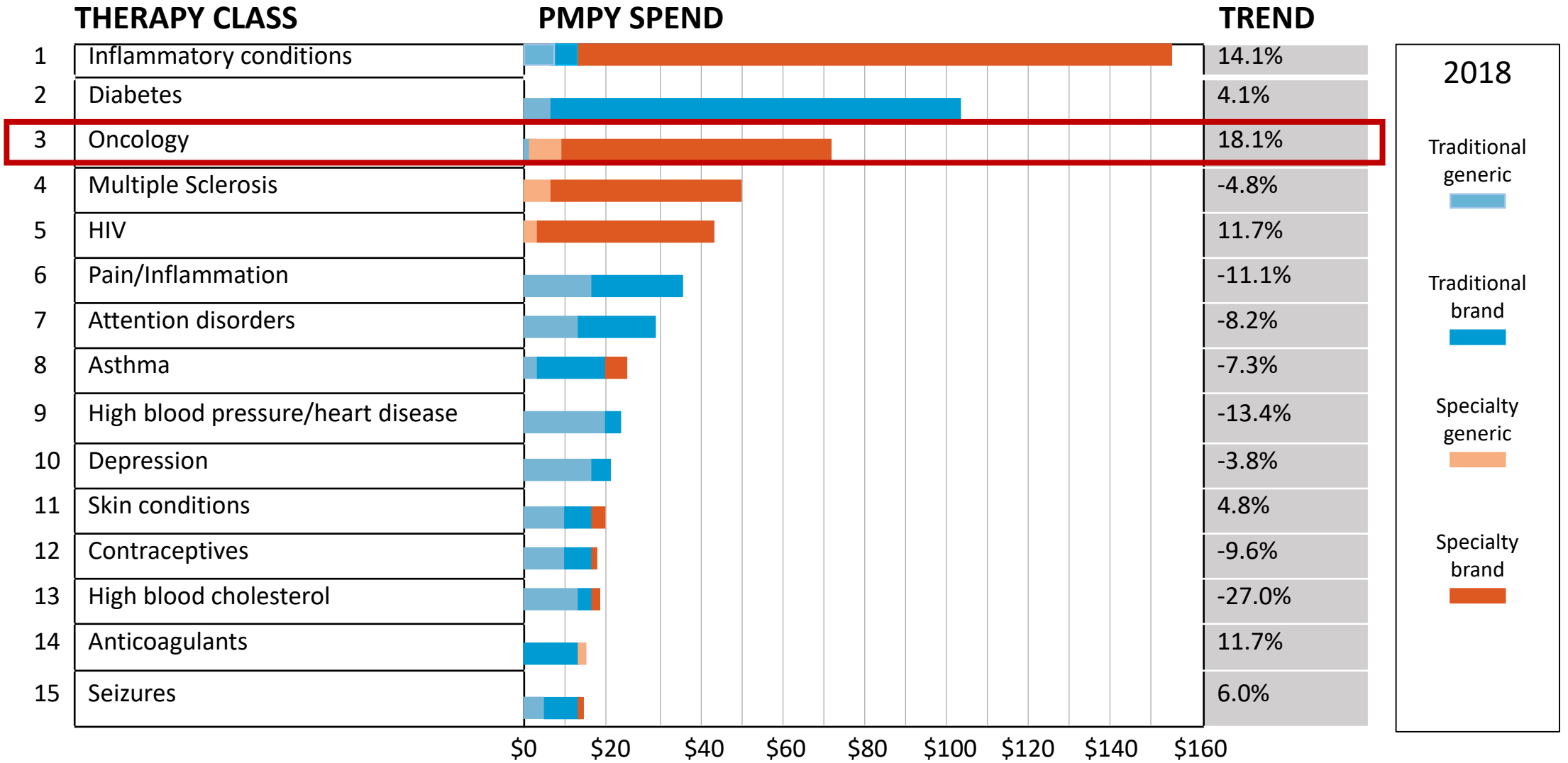
Minimal to no activity

Prostate cancer
MMR+ Colon cancer
Myeloma
Pancreatic Cancer
ER+ breast cancer

Medical and Pharmacy Benefit Design Strategies for Immuno-Oncology Agents

Jeffrey Dunn, PharmD, MBA
Vice President, Clinical Strategy and Programs and Industry Relations
Magellan Rx Management

Oncology Led All Classes of Drugs in Terms of Trend in 2018 with a Sizeable Specialty Component



Spending on Oncology Therapies has Risen Consistently for Several Decades

- 73 new cancer therapies approved or indications expanded since 2012
- 16 new cancer drugs approved in 2017, all targeted therapies
- Global spending on cancer medications rose from $96 billion in 2013 to $133 billion in 2017
  - US led the trend with highest spend: 33% (2013) to 50% (2017) of global spend
- US cancer drugs expected to cost $100 billion by 2022
- Median annual cost of new cancer drug doubled in last decade from $75,000 to $150,000
- 87% of cancer drugs are used by fewer than 10,000 patients each year
- 700 new molecules in late-stage development now

New Cancer Therapies Approved/Indications Expanded

2013	2014	2015	2016	2017	2018
12	10	21	11	16	3

Total US Spending Oncology Therapeutic Medicines, 2013-2017

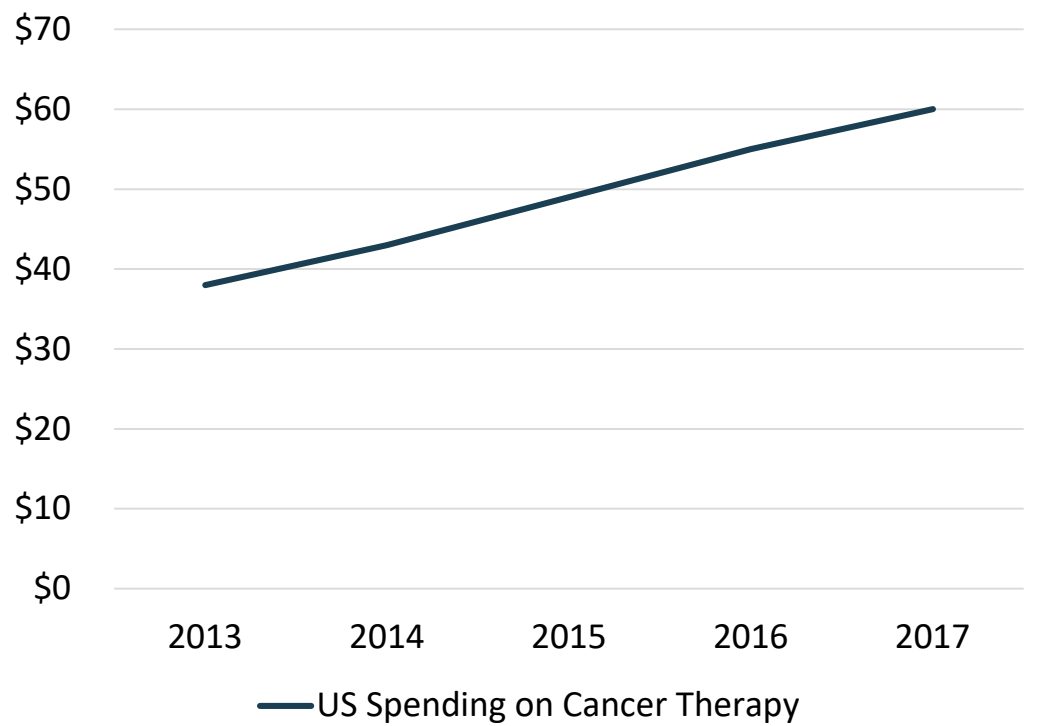


Chart Source: IQVIA, ARK R&D Intelligence, Dec 2017;
IQVIA Institute, Mar 2018, CenterWatch: FDA Approved Drugs for Oncology.

Attitudes Toward the Management of Oncology Therapies Have Long Since Changed: Cancer is No Longer Untouchable

Price and value of therapies rarely questioned

Vigorous debate about the overall value* of treatments

Payers now actively apply payment reforms and quality measurement to cancer services

*Clinical, pharmacoeconomic, humanistic, societal, etc.

Willingness to Manage Oncology

Oncology Management Strategies Willing to Implement

% of payers
(n = 45)

67%	**Restricting specified regimens based on the patient's performance status when aligned with NCCN recommendations**
67%	**Incentivizing lower cost regimes when they carry the same level of compendia recommendation**
47%	**Limiting agents that are recently approved by the FDA under an accelerated approval pathway to patients who meet the study eligibility criteria used for FDA approval**
31%	**Not covering NCCN 2A recommendations if evidence is lacking**
2%	**Other (preferring a lower cost agent but only if NCCN 1 vs. 2A or lower)**
7%	**None of the above**

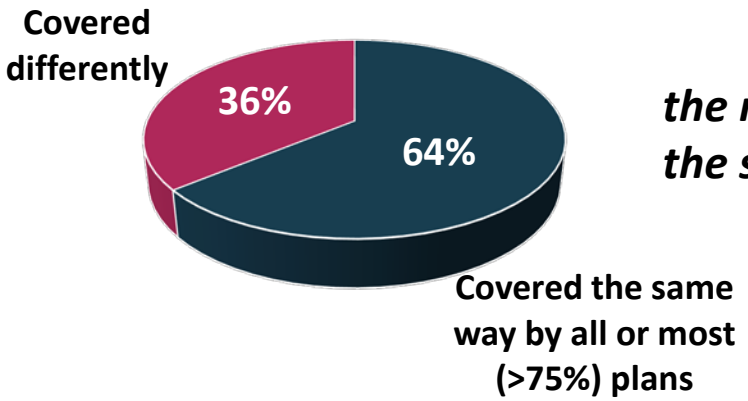
Magellan Rx Management Medical Pharmacy Trend Report 2018. Magellan Rx Website: https://www1.magellanrx.com/media/843213/2018_mrx_medical-pharmacy-trend-report.pdf. 2018. Accessed February 2019.

Formulary and Clinical Policy

- Closed formularies are becoming more common
  - NDC block until review
  - Increasing number of excluded drugs
- Narrowing the number of preferred or covered products
- More restrictive policies/PA criteria: going beyond the label to consider clinical trial inclusion/exclusion
  - Restricted patient population
  - Stopping rules for nonresponse
  - More rigorous re-authorization criteria

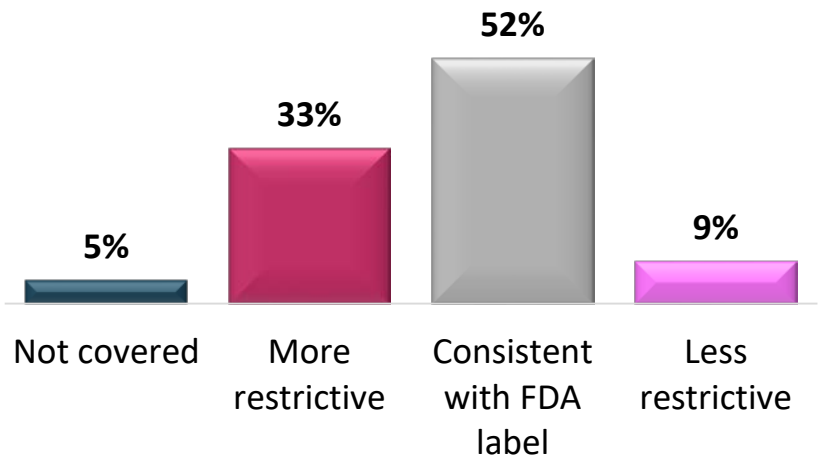
Tufts Study on Restrictive Coverage

Across 3,417 decisions addressing coverage for 302 drug indication pairs…



the majority were covered the same way…

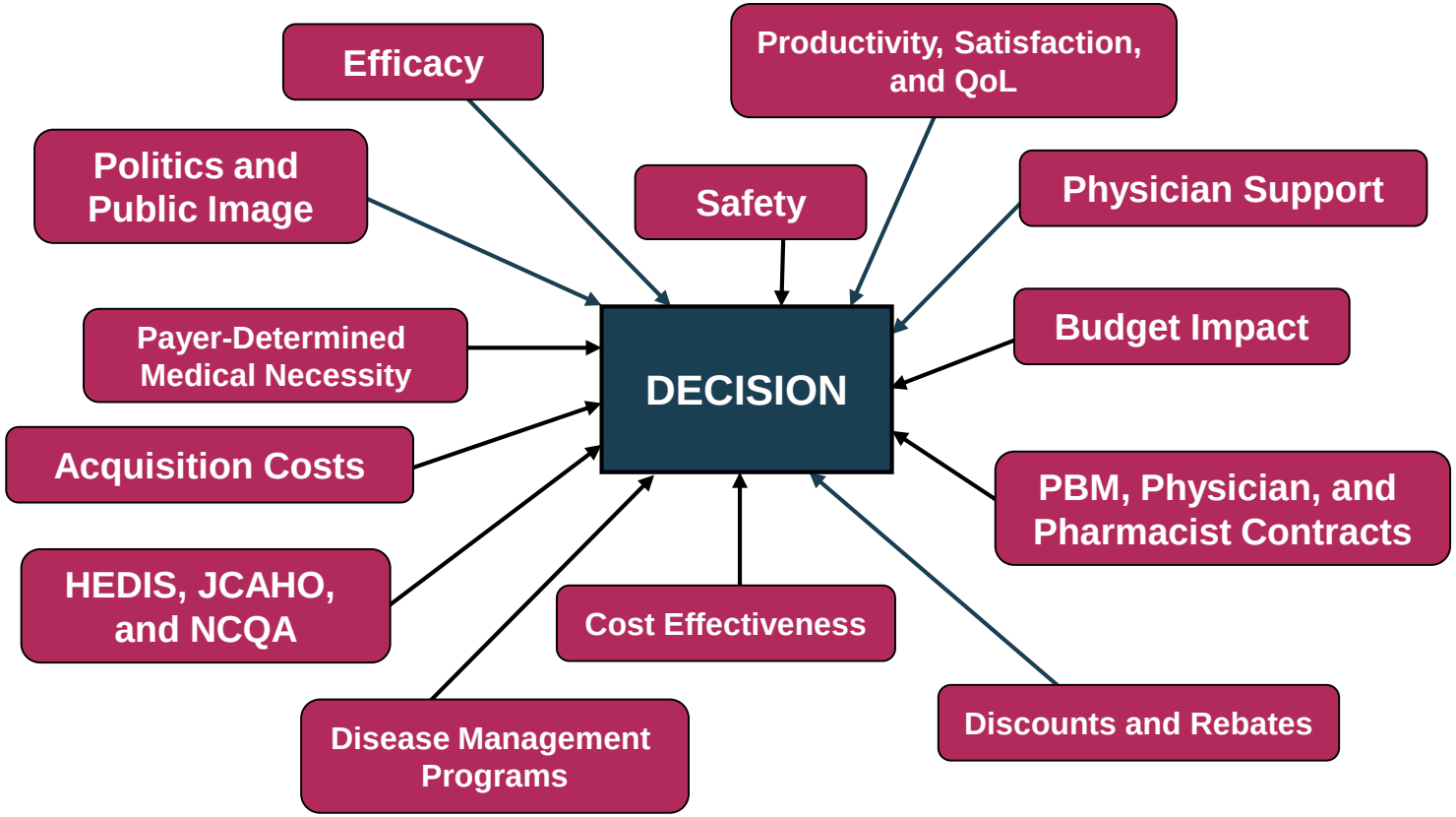
and specifically the decisions were…



- Health plans restricted coverage of drugs indicated for cancer less often than they did coverage of drugs indicated for other diseases
- Using multivariate regression, it was found that several drug-related factors were associated with less restrictive coverage, including indications for orphan diseases or pediatric populations, absence of safety warnings, time on the market, lack of alternatives, and expedited FDA review

Chambers JD, Kim DD, Pope EF, et al. *Health Affairs*. 2018;37(7):1041-47

Potential Factors in Oncology Formulary Decision Making



HEDIS = Healthcare Effectiveness Data and Information Set; JCAHO = Commission on Accreditation of Healthcare Organizations; NCQA = National Committee for Quality Assurance; PBM = pharmacy benefit manager.

Format for formulary submissions. Version 2.0. Academy of Managed Care Pharmacy. http://amcp.org/WorkArea/DownloadAsset.aspx?id=16276. Accessed August 2016.

Health Technology Assessment/Drug Review

- Payers are demonstrating more interest in Institute for Clinical Effectiveness Research (ICER) reviews and the potential for use of Cost Effectiveness Analysis (CER)
- Drug evaluation, contracting, etc. are contributing to large discrepancies between plan coverage and coverage policies

Use of ICER Reports by Payers

At what point were ICER reports used in the formulary decision process?

- 75% evidence source for preparing P&T recommendations
- 69% inform or validate the payer's own analysis
- 64% used during research process
- 56% used during the P&T review phase
- 33% use during coverage policy development

May 2015 Survey of AMCP eDossier Users (N=99)

Lising A. Rosner A, Gladman J, et al. *J Manag Care Pharm*. 2016;22(1-a) Suppl: S90-S91.

Clinical Evidence & Cost-Effectiveness

- Organizations choose whether to include cost data as part of the P&T Committee Review process
- If cost data is not included, drugs are reviewed solely on clinical efficacy, safety, unmet need
- An administrative committee is then tasked with final formulary placement decisions based on:
  - P&T Committee's clinical evaluation
  - Cost-effectiveness data

Available Oncology Value Frameworks

American Society of Clinical Oncology (ASCO) Value Framework

National Comprehensive Cancer Network (NCCN) Evidence Blocks

Memorial Sloan Kettering Cancer Center Drug Abacus

Institute for Clinical and Economic Review (ICER) Value Assessment Framework

European Society for Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale

Slomiany M, Madhavan P, Kuehn M, et al. *Am Health Drug Benefits*. 2017;10(5):253-60.

Emphasis of Various Oncology Value Frameworks

Value Framework[6-10]					
Emphasis	**ASCO**	**NCCN**	**MSKCC**	**ICER**	**ESMO**
Application					
Target stakeholder	Patient Physician	Patient Physician	Physician Policymaker	Payer Policymaker	Payer Policymaker
Conditions addressed	Oncology: solid, blood	Oncology: solid, blood, radiology, surgery	Oncology: solid, blood	All conditions, focus on new drugs of high impact	Oncology: solid, blood, radiology, surgery
Clinical trial data					
Breadth of evidence	1 trial, RCT	Published data, panel members' clinical experience, case reports	1 trial, registration trial of first indication (FDA label)	RCT meta-analysis and manufacturer- provided data	1 trial, RCT, comparative outcomes study, meta analysis
Trial sample size accounted	No	Yes	Yes	Yes	Indirectly, through lower bound of 95% CI
Allows for single-arm trials	Partially	Likely	Yes	Yes	No
Acknowledges trial contamination	No	Likely	No	Yes	Yes
Accounts for patient preference	No	Yes	Yes	No	No
Readout					
Outcomes	Net health benefit score	Evidence Blocks score	DrugAbacus price	Cost-effectiveness; budget impact	ESMO MCBS
Cost/price	Price (WAC or ASP+) per month or course of therapy	Affordability scale	Abacus price per month or course of therapy	Cost per year	Not specified, left to payers to evaluate

ASCO indicates American Society of Clinical Oncology; ASP, average sales price; CI, confidence interval; ESMO, European Society for Medical Oncology; FDA, US Food and Drug Administration; ICER, Institute for Clinical and Economic Review; MCBS, Magnitude of Clinical Benefit Scale; MSKCC, Memorial Sloan Kettering Cancer Center; NCCN, National Comprehensive Cancer Network; RCT, randomized controlled trial; WAC, wholesale acquisition cost.

Slomiany M, Madhavan P, Kuehn M, et al. *Am Health Drug Benefits*. 2017;10(5):253-60.

Inputs of Various Oncology Value Frameworks

Value Framework[6-10]					
Input	**ASCO 2.0**	**NCCN**	**MSKCC**	**ICER**	**ESMO**
Primary end points					
Efficacy	Advanced disease: HR (death), OS, PFS, response rate Adjuvant therapy: HR (death), OS, DFS	Vary, dependent on indication	Improvement in OS or surrogate end point	Vary, dependent on location	Advanced disease: OS, PFS, palliation of symptoms, response rate
Safety/toxicity	Based on side-effect frequency, grade	Effect on daily life	Grade 3/4; probability of discontinuing	Severe side effects	Grade 3/4; severe side effects
Secondary end points					
Treatment-free interval	Yes	No	No	No	No
Tail of the curve	Yes	No	No	No	No
Quality of life/palliation	Yes	No	No	Yes	Yes
Patient preferences	No	No	No	No	No
Epidemiologic factors					
Disease burden/incidence	No	No	Yes	Yes	No
Unmet need	No	No	Yes	No	No
R&D factors					
Novelty	No	No	Yes	No	No
Research cost	No	No	Yes	No	No
Cost					
Drug costs	Advanced disease: drug acquisition cost per month Adjuvant therapy: drug acquisition cost/entire treatment regimen	Total treatment cost	ASP/AWP	Total cost per person, total cost to payers	Not specified, left to payers to evaluate
Cost to healthcare system	No	Yes	Yes	Yes	No

ASCO indicates American Society of Clinical Oncology; ASP, average sales price; AWP, average wholesale price; DFS, disease-free survival; ESMO, European Society for Medical Oncology; HR, hazard ratio; ICER, Institute for Clinical and Economic Review; MSKCC, Memorial Sloan Kettering Cancer Center; NCCN, National Comprehensive Cancer Network; OS, overall survival; PFS, progression-free survival;; R&D, research and development.

Slomiany M, Madhavan P, Kuehn M, et al. *Am Health Drug Benefits*. 2017;10(5):253-60.

Scoring Algorithms of Various Oncology Value Frameworks

ASCO	NCCN	MSKCC	ICER	ESMO
Formulaic	Expert-based	Formulaic	Formulaic and expert-based	Formulaic

Slomiany M, Madhavan P, Kuehn M, et al. *Am Health Drug Benefits*. 2017;10(5):253-60.

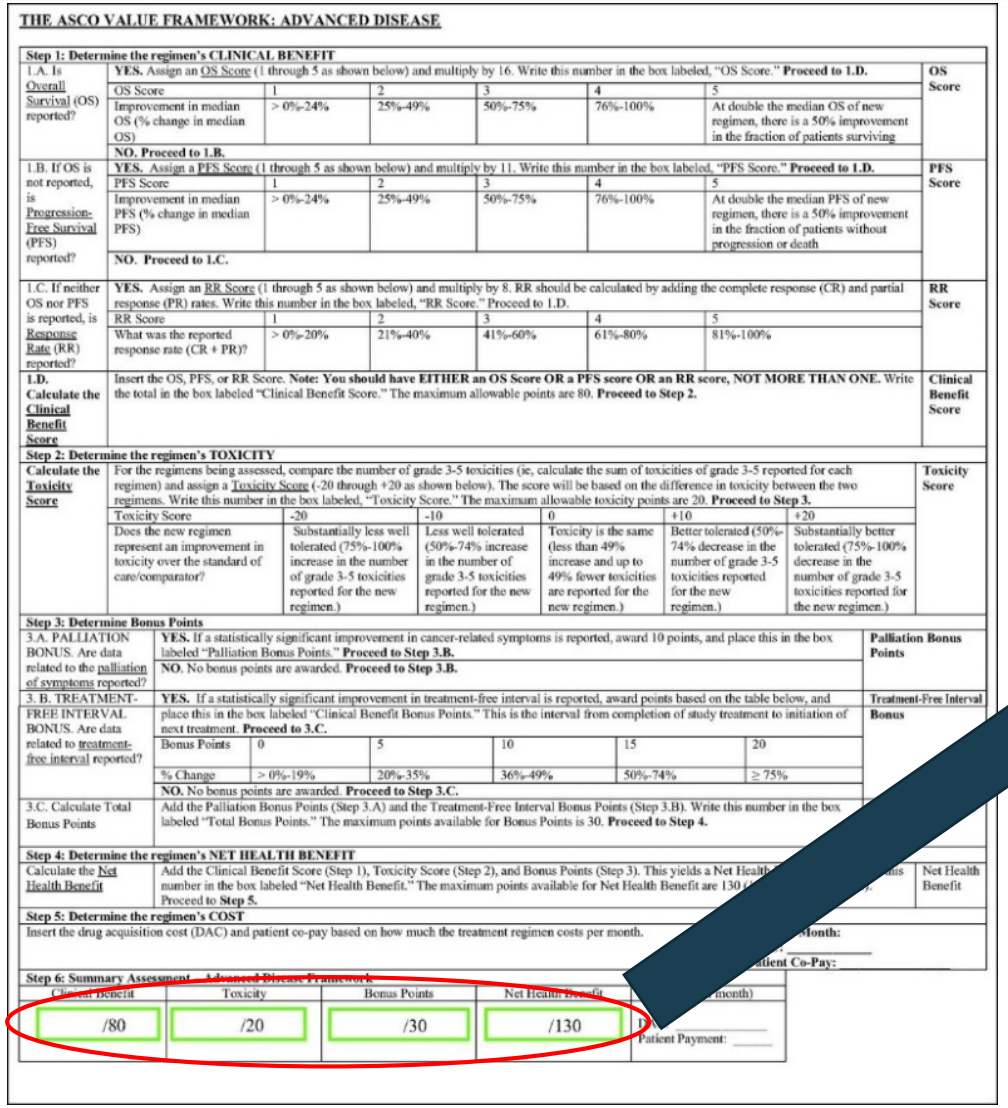
Outputs of Various Oncology Value Frameworks

Value Frameworks [6-10]					
Output	ASCO	NCCN	MSKCC	ICER	ESMO
Health benefit	Net health benefit	Score (1-5) for each 5 key measures displayed as Evidence Blocks	No	Assessment of care value (high/intermediate/low)	A relative ranking of the magnitude of clinically meaningful benefit
Cost Readout	Directly reported as regimen cost (WAC or ASP) Advanced disease: drug acquisition cost per month Adjuvant therapy: drug acquisition cost for entire treatment	Reported as relative affordability, considers overall cost of intervention (eg, cost of drug, infusions, supportive care, management)	DrugAbacus value-based price per month or course of therapy; a user-generated value assessment directly compared with reported Medicare payment limit, 106% ASP	Cost per-year; cost-effectiveness of drug, with recommendations on what drug price should be to be cost-effective	Not specified; left to payers to evaluate
Drug, cost, relative, or absolute value	Yes	Yes	Yes	Yes	No
Cost to patient	Yes	No	No	No	No
Cost to healthcare system	No	Total drug and medical costs	Rarity per budget impact	Incremental cost-effectiveness ratio and budget impact	No

ASCO indicates American Society of Clinical Oncology; ASP, average sales price; ESMO, European Society for Medical Oncology; ICER, Institute for Clinical and Economic Review; MSKCC, Memorial Sloan Kettering Cancer Center; NCCN, National Comprehensive Cancer Network; WAC, wholesale acquisition cost.

Slomiany M, Madhavan P, Kuehn M, et al. *Am Health Drug Benefits*. 2017;10(5):253-60.

These Value Frameworks Lend Insight to Payer-led Management Interventions



THE ASCO VALUE FRAMEWORK: ADVANCED DISEASE

Step 1: Determine the regimen's CLINICAL BENEFIT

1.A. Is Overall Survival (OS) reported?	**YES.** Assign an OS Score (1 through 5 as shown below) and multiply by 16. Write this number in the box labeled, "OS Score." **Proceed to 1.D.**						**OS Score**
	OS Score	1	2	3	4	5	
	Improvement in median OS (% change in median OS)	> 0%-24%	25%-49%	50%-75%	76%-100%	At double the median OS of new regimen, there is a 50% improvement in the fraction of patients surviving	
	NO. Proceed to 1.B.						
1.B. If OS is not reported, is Progression-Free Survival (PFS) reported?	**YES.** Assign a PFS Score (1 through 5 as shown below) and multiply by 11. Write this number in the box labeled, "PFS Score." **Proceed to 1.D.**						**PFS Score**
	PFS Score	1	2	3	4	5	
	Improvement in median PFS (% change in median PFS)	> 0%-24%	25%-49%	50%-75%	76%-100%	At double the median PFS of new regimen, there is a 50% improvement in the fraction of patients without progression or death	
	NO. Proceed to 1.C.						
1.C. If neither OS nor PFS is reported, is Response Rate (RR) reported?	**YES.** Assign an RR Score (1 through 5 as shown below) and multiply by 8. RR should be calculated by adding the complete response (CR) and partial response (PR) rates. Write this number in the box labeled, "RR Score." Proceed to 1.D.						**RR Score**
	RR Score	1	2	3	4	5	
	What was the reported response rate (CR + PR)?	> 0%-20%	21%-40%	41%-60%	61%-80%	81%-100%	
1.D. Calculate the Clinical Benefit Score	Insert the OS, PFS, or RR Score. **Note: You should have EITHER an OS Score OR a PFS score OR an RR score, NOT MORE THAN ONE.** Write the total in the box labeled "Clinical Benefit Score." The maximum allowable points are 80. **Proceed to Step 2.**						**Clinical Benefit Score**

Step 2: Determine the regimen's TOXICITY

Calculate the Toxicity Score	For the regimens being assessed, compare the number of grade 3-5 toxicities (ie, calculate the sum of toxicities of grade 3-5 reported for each regimen) and assign a Toxicity Score (-20 through +20 as shown below). The score will be based on the difference in toxicity between the two regimens. Write this number in the box labeled, "Toxicity Score." The maximum allowable toxicity points are 20. **Proceed to Step 3.**						**Toxicity Score**
	Toxicity Score	-20	-10	0	+10	+20	
	Does the new regimen represent an improvement in toxicity over the standard of care/comparator?	Substantially less well tolerated (75%-100% increase in the number of grade 3-5 toxicities reported for the new regimen.)	Less well tolerated (50%-74% increase in the number of grade 3-5 toxicities reported for the new regimen.)	Toxicity is the same (less than 49% increase and up to 49% fewer toxicities are reported for the new regimen.)	Better tolerated (50%-74% decrease in the number of grade 3-5 toxicities reported for the new regimen.)	Substantially better tolerated (75%-100% decrease in the number of grade 3-5 toxicities reported for the new regimen.)	

Step 3: Determine Bonus Points

3.A. PALLIATION BONUS. Are data related to the palliation of symptoms reported?	**YES.** If a statistically significant improvement in cancer-related symptoms is reported, award 10 points, and place this in the box labeled "Palliation Bonus Points." **Proceed to Step 3.B.**						**Palliation Bonus Points**
	NO. No bonus points are awarded. **Proceed to Step 3.B.**						
3. B. TREATMENT-FREE INTERVAL BONUS. Are data related to treatment-free interval reported?	**YES.** If a statistically significant improvement in treatment-free interval is reported, award points based on the table below, and place this in the box labeled "Clinical Benefit Bonus Points." This is the interval from completion of study treatment to initiation of next treatment. **Proceed to 3.C.**						**Treatment-Free Interval Bonus**
	Bonus Points	0	5	10	15	20	
	% Change	> 0%-19%	20%-35%	36%-49%	50%-74%	≥ 75%	
	NO. No bonus points are awarded. **Proceed to Step 3.C.**						
3.C. Calculate Total Bonus Points	Add the Palliation Bonus Points (Step 3.A) and the Treatment-Free Interval Bonus Points (Step 3.B). Write this number in the box labeled "Total Bonus Points." The maximum points available for Bonus Points is 30. **Proceed to Step 4.**						

Step 4: Determine the regimen's NET HEALTH BENEFIT

Calculate the Net Health Benefit	Add the Clinical Benefit Score (Step 1), Toxicity Score (Step 2), and Bonus Points (Step 3). This yields a Net Health number in the box labeled "Net Health Benefit." The maximum points available for Net Health Benefit are 130 (Proceed to **Step 5.**	Net Health Benefit

Step 5: Determine the regimen's COST

Insert the drug acquisition cost (DAC) and patient co-pay based on how much the treatment regimen costs per month. Month: _____ atient Co-Pay: _____

Step 6: Summary Assessment ~~Advanced Disease Framework~~

Clinical Benefit	Toxicity	Bonus Points	Net Health Benefit	month)
/80	/20	/30	/130	Patient Payment: _____

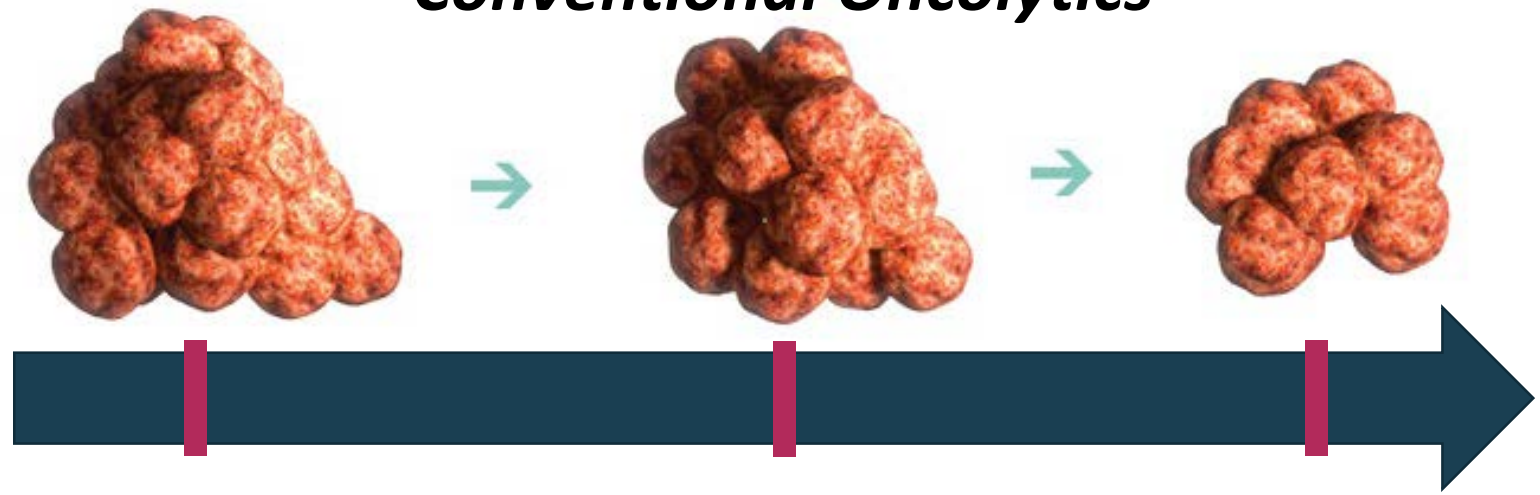
Score for individual agents or regimens based on efficacy, safety, and cost

- **Formulary Positioning**
- **Step Edits**
- **Clinical Pathways**

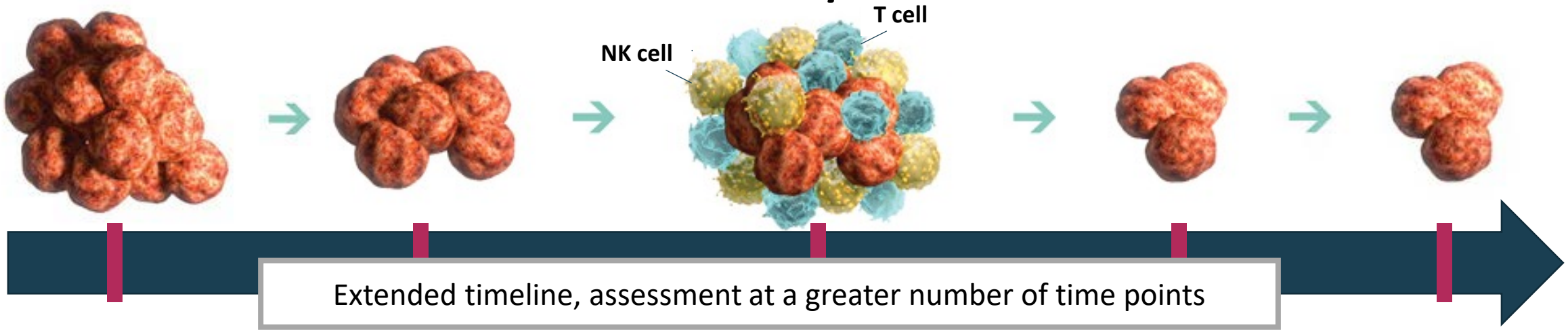
Schnipper LE, Davidson NE, Wollins DS, et al. *J Clin Oncol*. 2015;33(23):2563-77.

Fundamental Differences Between I-O Therapies and Conventional Oncolytics Necessitate an Advanced Approach to Drug Evaluation

Conventional Oncolytics

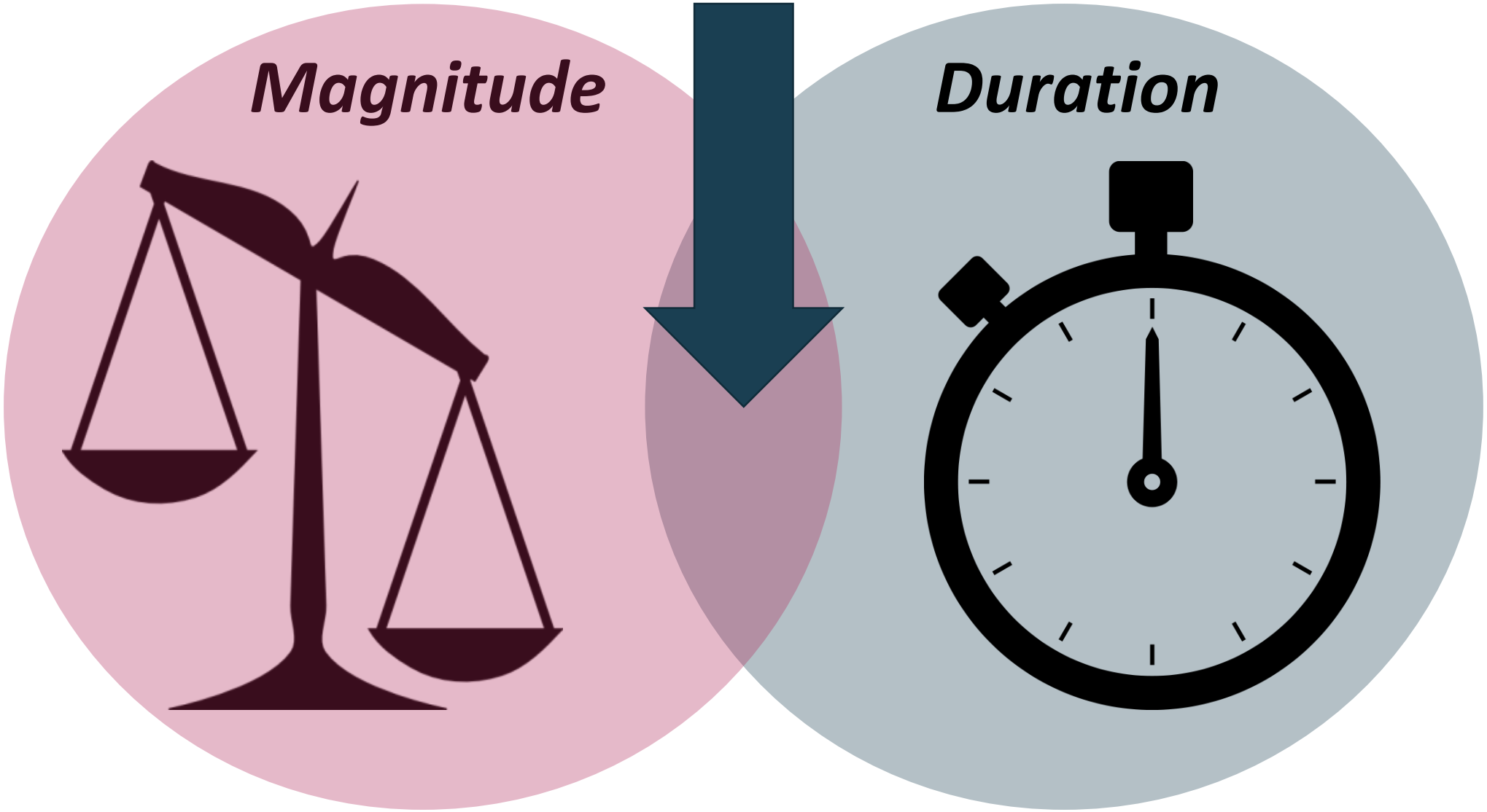


I-O Therapies



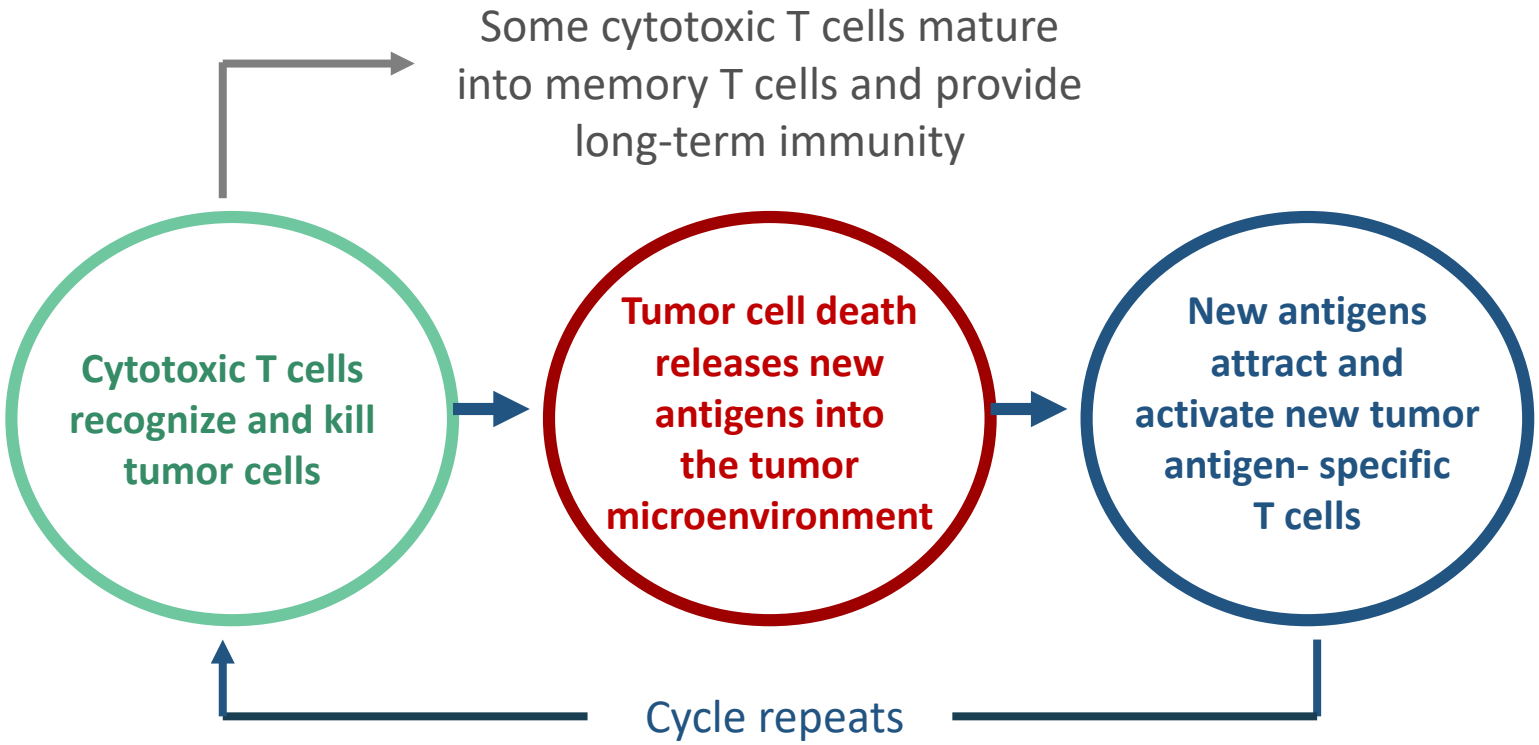
Extended timeline, assessment at a greater number of time points

Magnitude and Duration Are Both Key Measures of Response for I-O Therapies



Immune Response with I-O Therapies Can Deepen and be Sustained Over Time

The immune response evolves and expands over time by constantly recognizing and remembering tumor antigens.



As the immune response continues to expand, some cytotoxic T cells mature into memory T cells that may provide long-term immune protection, even if the original stimulus is no longer present.

Lau LL, Jamieson BD, Somasundaram T, Ahmed R. *Nature*. 1994;369(6482):648-52. Chen DS, Mellman I. *Immunity*. 2013;39(1):1-10.
Markiewicz MA, Fallarino F, Ashikari A, Gajewski TF. *Int Immunol*. 2001;13(5):625-32. Kaech SM, Wherry EJ, Ahmed R. *Nat Rev Immunol*. 2002;2(4):251-62.

Value Frameworks May Not Be Adequately Calibrated for the Assessment of I-O Agents

- Twenty-three metastatic indications for 6 I-O agents were approved by the FDA from March 2011 to August 2017
  - Ten (43%) of the approvals were based on survival end points, while 13 (57%) were based on response rates
- Only 3 drug indications fulfilled the threshold defined for the survival rate of patients receiving standard care (minimum 20%) in the ASCO framework
- Nine indications achieved the required level of improvement in proportion to patients alive in the test regimen compared with the standard (above 50%)
- There was overlap between these 2 criteria for 3 drug indications, allowing them to gain the durable survival bonus points awarded by the ASCO framework
- Durable survival and response rates of modern I-O agents are rarely recognized as significant by current oncology value frameworks
  - This may be due to insufficient demonstration of efficacy of such agents or inappropriately calibrated value frameworks

Ben-aharon O, Magnezi R, Leshno M, Goldstein DA. *JAMA Oncol*. 2018;4(3):326-332.

Considerations on Pseudo-progression with I-O Therapies

While uncommon, pseudo-progression is an important consideration when evaluating response to I-O therapies

	Disease progression	Pseudo-progression
Performance status	Deterioration of performance	Remains stable or improves
Systemic symptoms	Worsen	May or may not improve
Symptoms of tumor enlargement	Present	May or may not be present
Tumor burden		
Baseline	Increase	Initial increase followed by response
New lesions	Appear and increase in size	Appear then remain stable and/or subsequently respond
Biopsy may reveal	Evidence or tumor growth	Evidence of immune-cell infiltration

Wolchok JD, Hoos A, O'day S, et al. *Clin Cancer Res*. 2009;15(23):7412-20.
Hales RK, Banchereau J, Ribas A, et al. *Ann Oncol*. 2010;21(10):1944-51.
Eisenhauer EA, Therasse P, Bogaerts J, et al. *Eur J Cancer*. 2009;45(2):228-47.

Safety Considerations: Immune-mediated Adverse Reactions (imARs)

I-O Therapies that modulate immune pathways may enable the immune system to attack healthy cells along with tumor cells: these events are known as imARs

Throughout I-O treatment, HCPs should engage in the following:

- Educate and encourage patients and caregivers to monitor for and report symptoms of imARs
- Remain vigilant throughout and after treatment to minimize complications, some of which may be life threatening
- Use treatment algorithms to assist in managing immune-mediated Adverse Reactions

As research in immune system activation advances and more data are made available, understanding and appropriate management of imARs will evolve

Amos SM, Duong CP, Westwood JA, et al. *Blood*. 2011;118(3):499-509.
Gelao L, Criscitiello C, Esposito A, Goldhirsch A, Curigliano G. *Toxins (Basel).* 2014;6(3):914-33.
Bertrand A, Kostine M, Barnetche T, Truchetet ME, Schaeverbeke T. *BMC Med*. 2015;13:211.

Specialty Management Trends

- Utilization Management
  - Prior Authorization
  - Step Therapy
  - Quantity Limits
  - Site-of-Care Restrictions
  - ICER Evaluations
- Benefit Design
  - Specialty Formulary
  - Tier Status
  - Medical vs Pharmacy Benefit
  - Co-insurance/Deductibles
  - OOP Limitations
- Channel Management
  - Site of Care
  - Retail vs Specialty
- Coordination of Care
  - Disease Management
  - Specialty Care Management
- Contracting/Rebates
  - Preferred Products
  - Formulary Exclusions
  - Closed Formularies
  - Price Protection

Summary

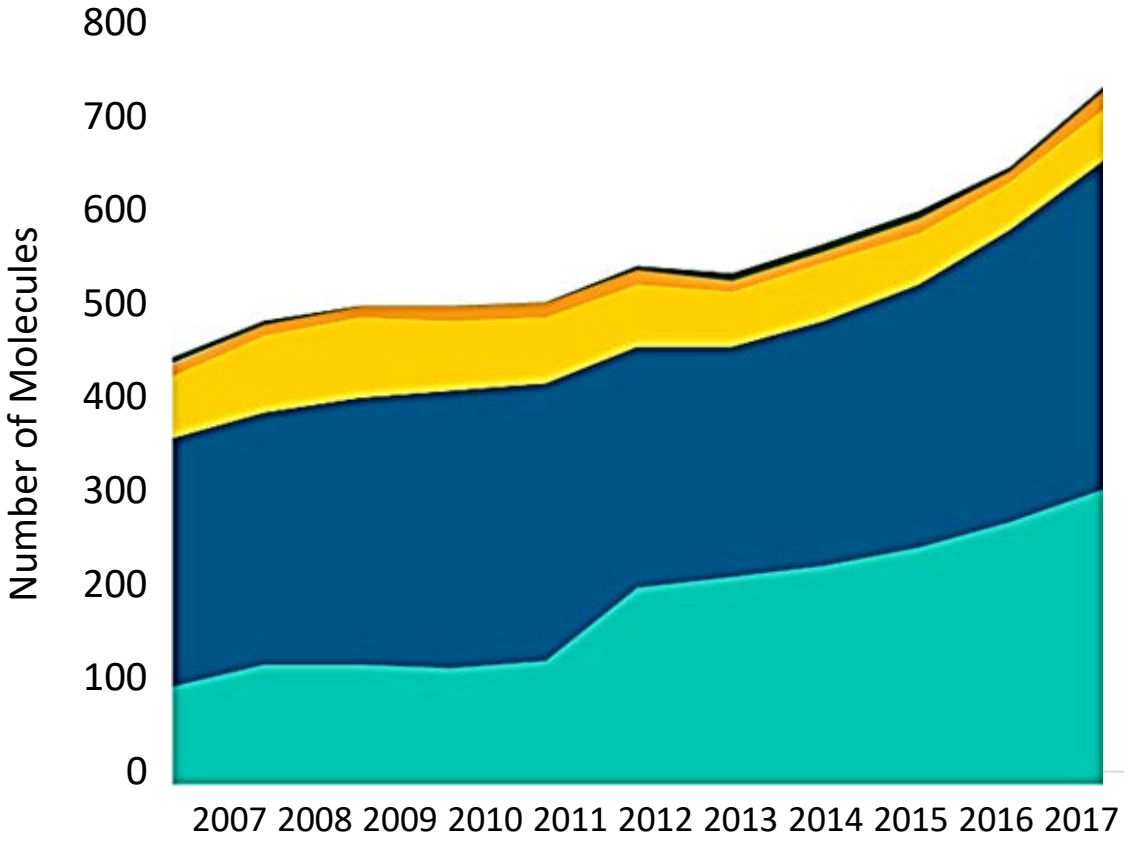
- The specialty drug spend and trend for oncology has risen significantly and currently leads other classes in terms of growth
- Payer decision makers are increasingly tasked with managing these agents to provide quality health care that is economically sustainable
- Formulary decisions based on available evidence and value frameworks are crucial in managing the drug trend, but may require a revised approach for I-O agents
- A comprehensive evaluation of outcomes at various time points, incorporating both magnitude and duration of response is necessary for an accurate assessment of I-O agents
- A coordinated specialty management strategy is essential

Health Plan Strategies to Enhance Patient Outcomes with Immuno-Oncology Agents

John Fox, MD, MHA
Vice President, Associate Chief Medical Officer
Medical Affairs
Priority Health

An Increasing Number of Targeted Oncology Agents are Being Developed

The Pipeline of Late Phase Oncology Molecules, 2007-2017



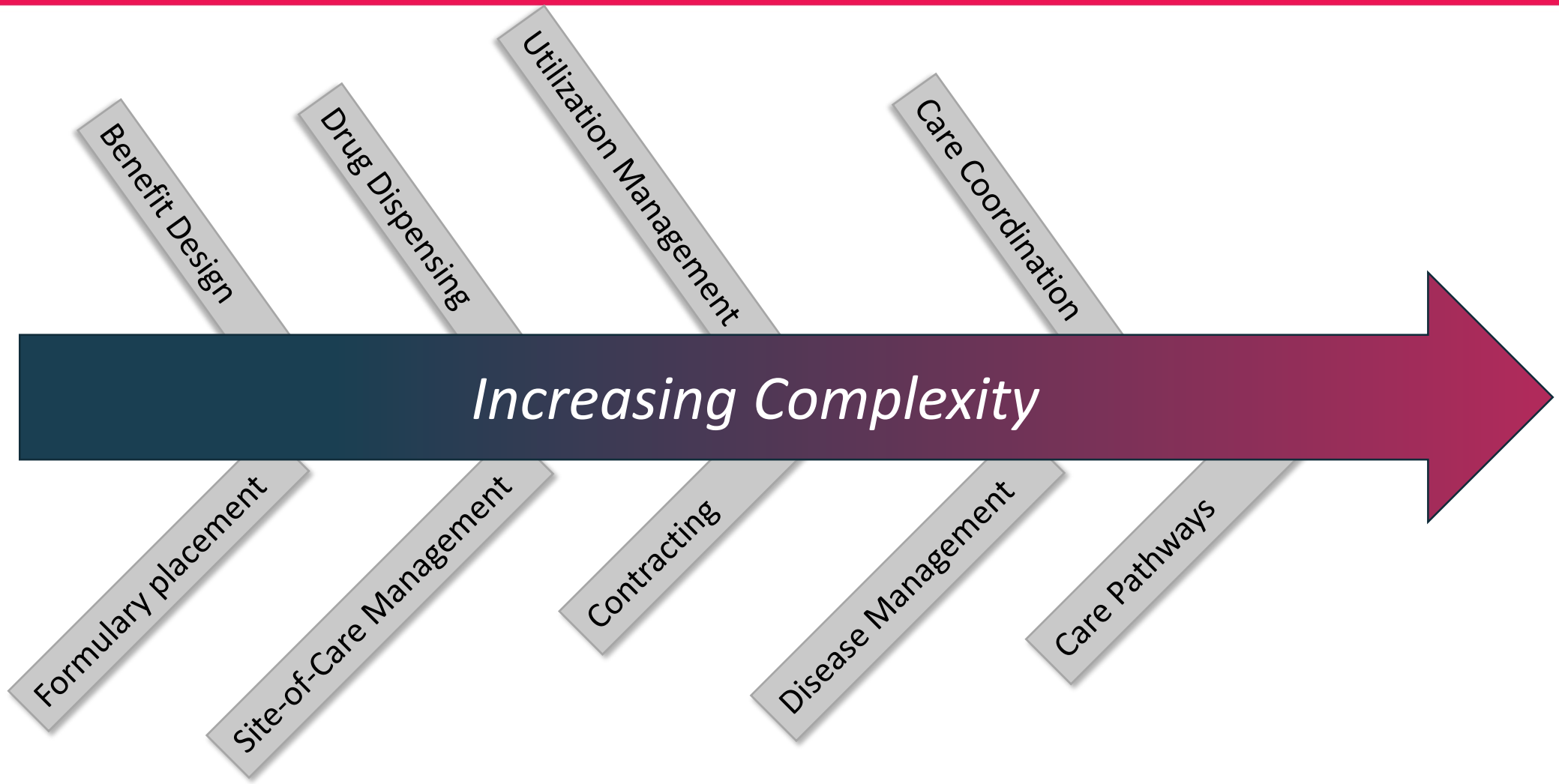
Year	2007 (434)	2017 (710)
Radiotherapies	0.9% (4)	0.4% (3)
Hormonals	3% (14)	2% (17)
Cytotoxics	15% (63)	8% (54)
Targeted Small Molecule	59% (254)	47% (335)
Targeted Biologics	23% (99)	42% (301)

Evolution of Treatment Development

Immuno-Oncology (I-O) Therapies

Global Oncology Trends 2018. IQVIA. https://www.iqvia.com/institute/reports/global-oncology-trends-2018. Published May 24, 2018. Accessed February 2019.

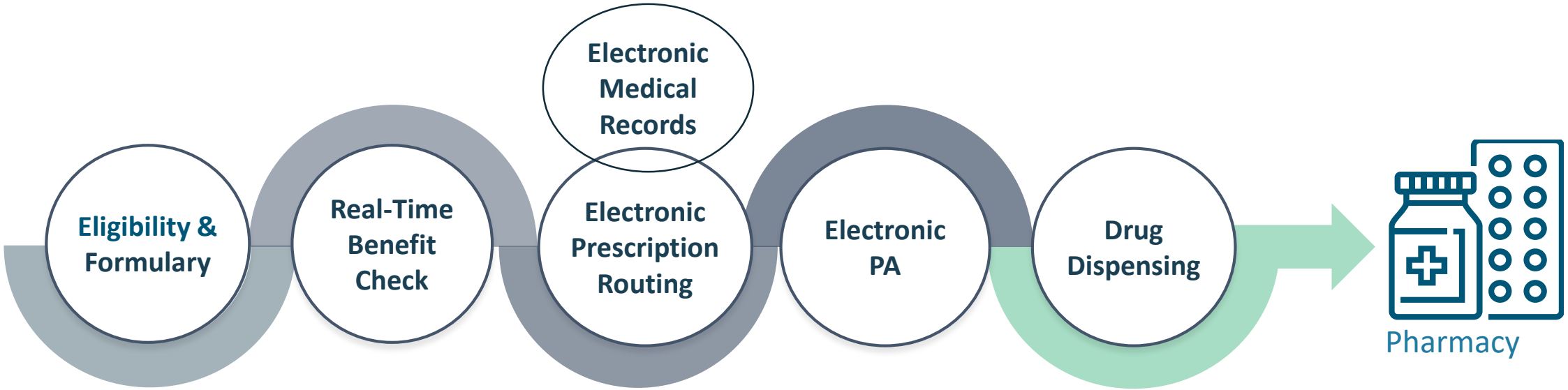
Payers Have a Number of Levers for Managing Oncology Drug Therapies



Utilization Management Strategies

- Formulary management including cross benefit management
- Prior authorization (PA)
- Step therapy (ST)
- Quantity limits (QL) for oral therapies
- Dose and vial size monitoring for infused drug
- Edits

Data Management and Support Can Streamline Patient Access and Drug Dispensation



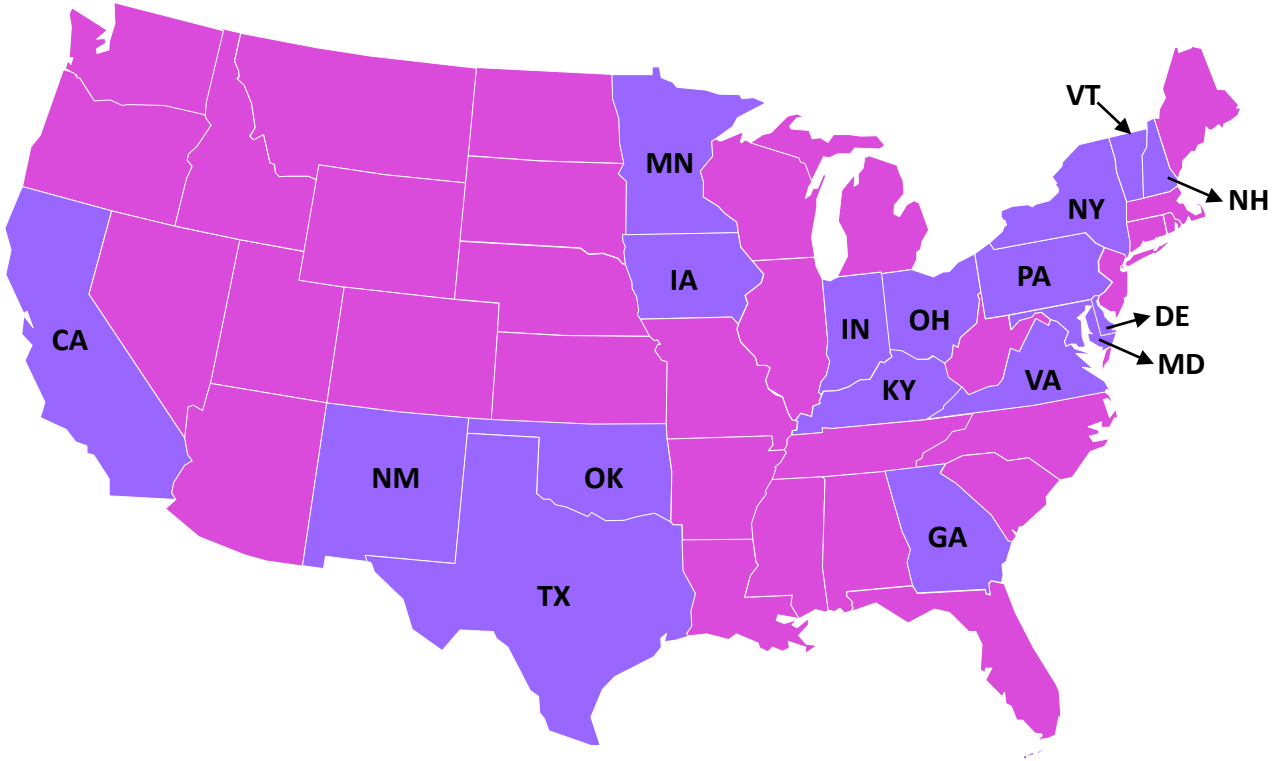
The services should:

- Exchange information so that the prescriber (staff) only needs to enter it once
- Have a common “ID” so that the different transactions can be linked by multiple entities at different times
- Complete all actions required to get the patient on the right medication as soon as possible
- Integration of electronic medical records (EMRs) potentiates efficiency

Evolving Restrictions on Established Utilization Management Processes

- 17 states require all commercial health care plans to use a an electronic prior authorization form in compliance with a national standard.
- Several states set time limits for prior authorization approvals.
- At least 18 states require exceptions to step therapy, specify time limits to respond to override requests or limit time step therapy can be mandated.
- Some states prohibit use of step therapy for patients who have gone through it previously with another health plan.

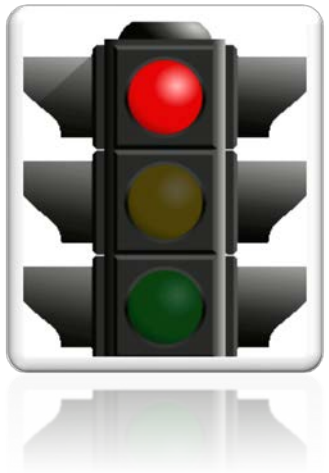
States Requiring Electronic Prior Authorization in Compliance with the NCPDP SCRIPT Standard



NCPDP=National Council for Prescription Drug Programs

ePA National Adoption Scorecard. CoverMyMeds: https://www.covermymeds.com/main/pdf/cmm-scorecard-2018.pdf. Published 2018. Accessed March 2019.

Oncology PA: The Role of Companion and Complimentary Diagnostics



Companion Diagnostics

- Specified on the drug label (21 therapies to date, >50% in NSCLC)
  - e.g., ALK+ for crizotinib in NSCLC
- Typically among inclusion criteria for pivotal trials
- Required for PA

Complimentary Diagnostics

- Predictive of response but not required
  - KRAS/NRAS/BRAF for cetuximab in colorectal cancer
- Assay may be integrated into pivotal trials but not part of inclusion criteria
- May be incorporated into more rigorous PA requirements

Hersom M, Jorgensen JT. *Ther Drug Monit*. 2018;40(1):9-16.

Oncology PA: Current and Potential Future Criteria for I-O Agents

- A number of PD-1/L1 checkpoint inhibitors feature companion and complimentary diagnostics that may be incorporated into PA criteria
- These assays are based on PD-L1 titers predictive of response
- Companion Diagnostics:
  - PD-L1 immunohistochemical (IHC) 22C3 pharmDx assay for pembrolizumab
  - Ventana PD-L1 for atezolizumab
- Complimentary Diagnostics:
  - PD-L1 IHC 28-8 pharmDx for nivolumab
  - Ventana PD-L1 for durvalumab
- Role of lab developed tests vs. FDA approve tests

Hersom M, Jorgensen JT. *Ther Drug Monit*. 2018;40(1):9-16.

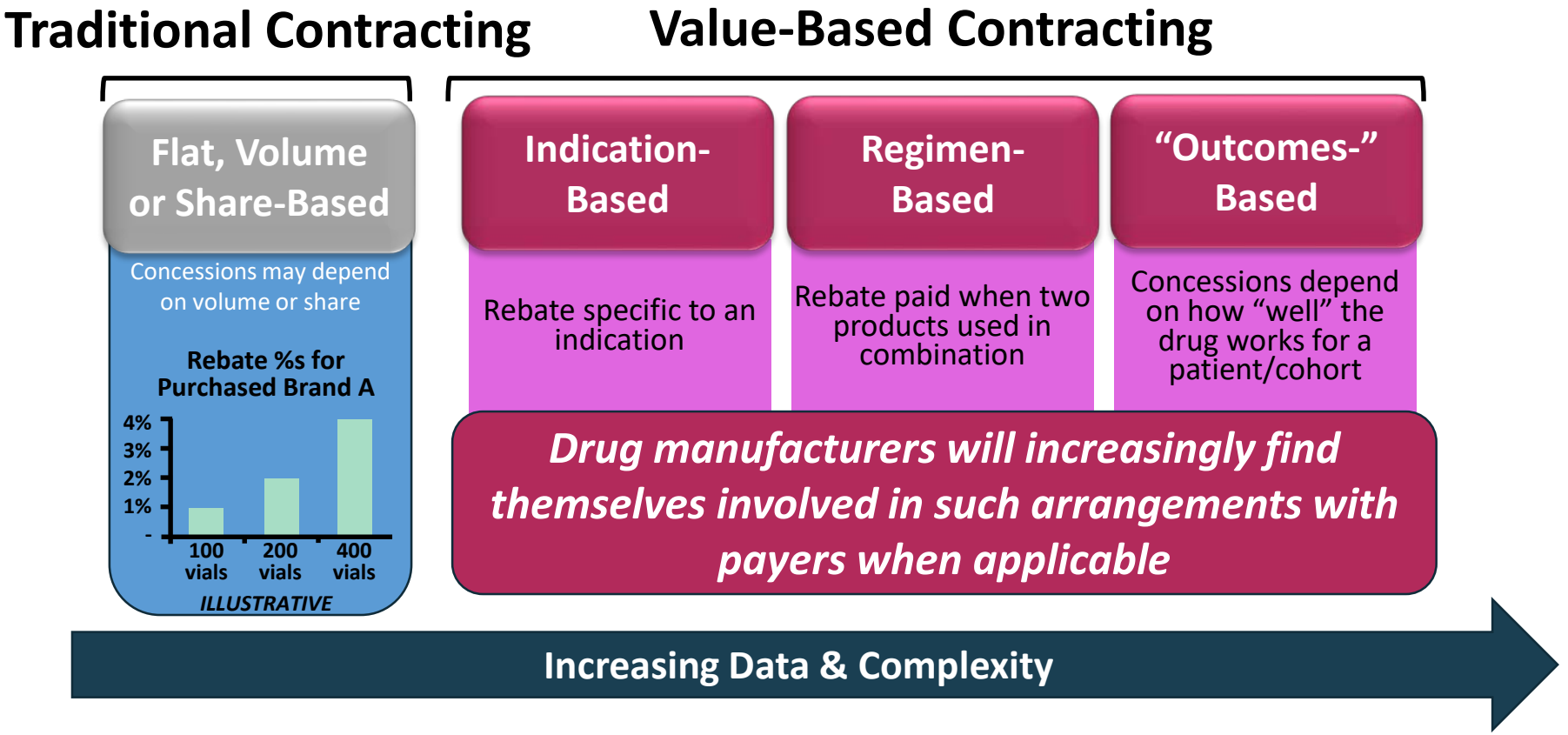
Balancing Benefit Design and Member Cost-Sharing Levers

- **Member cost-sharing**
  - High financial toxicity
  - High cost share reduces access to care for many patients
  - Adherence declines as cost rises, which may overall healthcare costs
- **Benefit design factors**
  - Medical vs pharmacy
  - Copay vs coinsurance/deductibles
    - Copay accumulator programs
  - Medicare Part B step therapy
  - Specialty tiers
  - In-network vs out-of-network

Donahue, M. Future of Health Care Delivery and Benefits. Anthem. Accessed March 2019 at https://slideplayer.com/slide/5926878/

Specialty Drug Contracting Approaches

45% of private payers were involved in pay-for-performance and risk-sharing programs in 2010; the number rose to 62% in 2013, and usage of these programs was estimated to be as high as 75% in 2016



Long G, Mortimer R, Sanzenbacher G. *J Med Econ*. 2014;17(12):883-93.

CMS OCM Program

- 5-year episode-of-care (EOC) program applicable to high-volume cancers (expected to cover 90% of cancer types)
- Medicare FFS program as part of a multi-payer model—applies to physician practices and PSA arrangements for provider-based services; but not to PPS exempt cancer hospitals
- Medicare pays $160 per beneficiary per month (PBPM) for a 6-month EOC ($960 per EOC), plus a retrospective performance-based payment
  - Payments in addition to Medicare FFS payment
- Performance-based payments (semi-annual)
  - Based on meeting applicable quality measures (preliminary set specified) – “performance multiplier” determines % of performance-based payment
  - Based on reducing cost at least 8% below a target threshold, with a 20% cap
  - Two-side risk allowed by no takers (yet)

Contracting with High-Quality, Cost-Efficient Providers: Oncology Practices

- The most cost-effective oncology practices shared several key attributes ostensibly linked to an integrated care approach:
  - multicomponent health care system
  - conservative use of imaging
  - ongoing discussion of treatment options, risks, and benefits
  - early and standardized palliative care referrals
  - expanded access to ambulatory rapid response and same day management
  - optimized use of RNs for appropriate clinical interventions (proactive outreach, telephonic advice/triage for ED avoidance, hospital use avoidance)

Blayney DW, Simon MK, Podtschaske B, et al. *JAMA Oncol*. 2018;4(2):164-171.

Care Coordination Improves Outcomes

NCI Study

- Meta-analysis of 52 studies found care coordination improved 81% of outcomes, including screening, patient experience, quality end-of-life care
- Most common care programs were:
  - Patient navigation
  - Home telehealth
  - Nurse case management

Gorin SS, Haggstrom D, Han PKJ, Fairfield KM, Krebs P, Clauser SB. *Ann Behav Med*. 2017;51(4):532-546.

Care Coordination Reduces Confusion and Costs

Meridian Health Systems:

- Care coordinator communicates with patient, family, multiple specialists
- Reduces unnecessary imaging and testing
- Reduces hospitalizations from manageable complications such as dehydration.
- Earns patient satisfaction scores higher than 90%

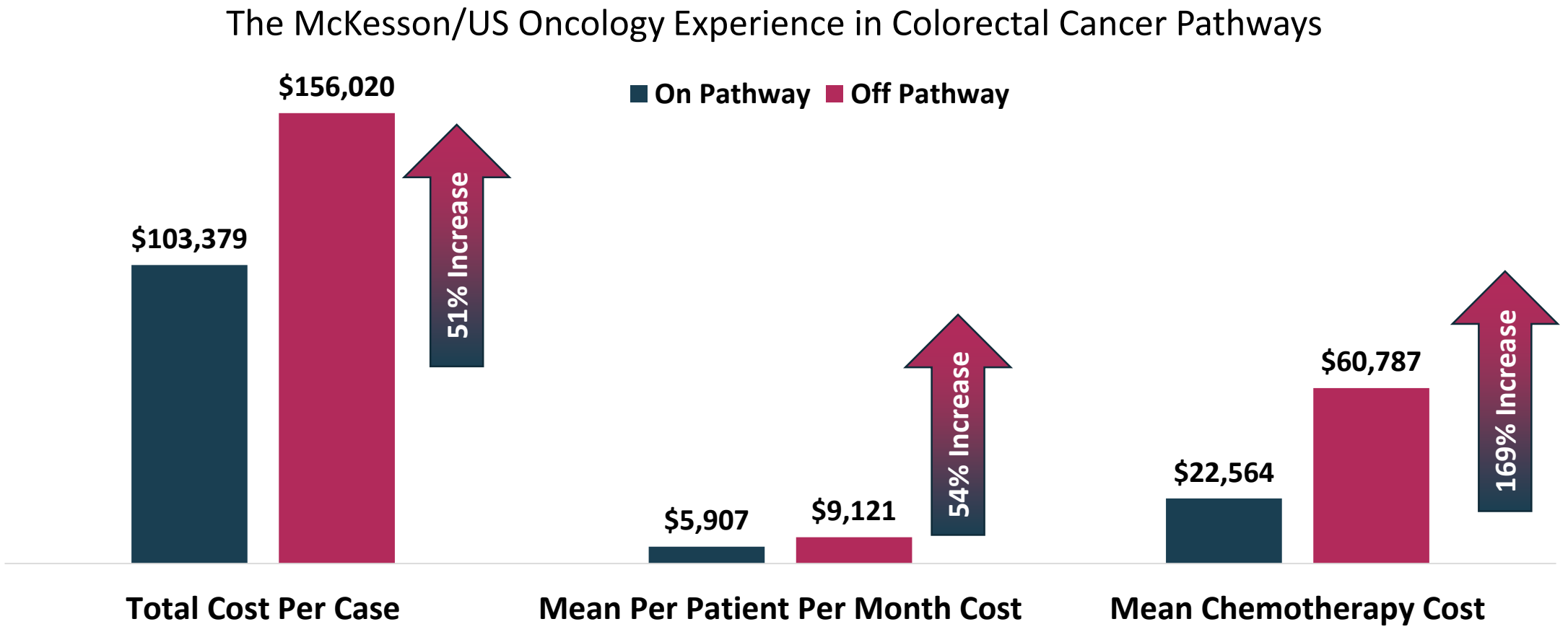
Cryts A. Improve Care Coordination in Cancer Care: 2 Key Focus Areas. *Managed Healthcare Executive*. Published online March 16, 2018. https://www.managedhealthcareexecutive.com/leukemia-and-lymphoma/improve-care-coordination-cancer-care-2-key-focus-areas

Health Coaching Component of Care Coordination Reduces Costs, Increase Satisfaction

- **Stanford**
  - Health coaches discuss goals for life with advanced cancer patients facing treatment failure or with less than three-year anticipated survival at diagnosis
    - Estimated reduction in costs, mostly from end-of-life care, of 14.5%
  - Health coach/nurse team assessed symptoms at intervention call center using decision-support systems.
    - Pre-stocked, individualized medication bundles were made available
    - Decreased ED visits, hospitalizations
    - Estimated cost reduction of 14%

Patel MI, Moore D, Milstein A. *J Oncol Pract*. 2015;11(4):280-4.

Pathways Have Been Associated with Cost Savings in Oncology

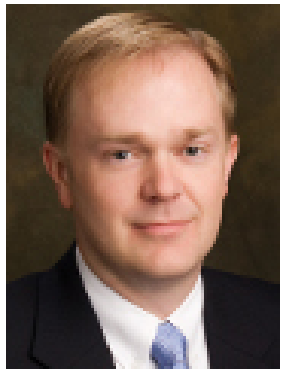


Hoverman JR, Cartwright TH, Patt DA, et al. *J Oncol Pract*. 2011;7(3 Suppl):52s-9s.

Summary

- Oncology treatment costs continue to rise sharply, driven by multi-therapy regimens and targeted therapies
- Utilization management more important than ever, but some traditional methods are now legislatively restricted and new ones may have unintended negative consequences
  - For I-O therapy specifically, companion and complimentary diagnostics may play a role in PA criteria according to predicted response
- In addition to streamlined PA methodology and site-of-care initiatives, disease management, care coordination, and clinical pathways offer innovative solutions in oncology management

Faculty Idea Exchange



Jeffrey Dunn, PharmD, MBA
Vice President, Clinical Strategy and Programs and Industry Relations
Magellan Rx Management

John Fox, MD, MHA
Vice President, Associate Chief Medical Officer
Medical Affairs
Priority Health

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Please go to www.impactedu.net/cpe
Enter code: **immuno19**

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For Pharmacists: upon receipt of the completed evaluation form, you will receive an email within 3 weeks with a link and directions to submit your credit to the NABP CPE Monitor Service. **Pharmacists have up to 30 days to complete the evaluation and claim credit for participation so that information can be submitted to CPE Monitor as required.**

THE IMMUNO-ONCOLOGY TRANSFORMATION:

Implications for Managed Care

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