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Management of Expensive Drugs by US Insurers and Physician Organizations

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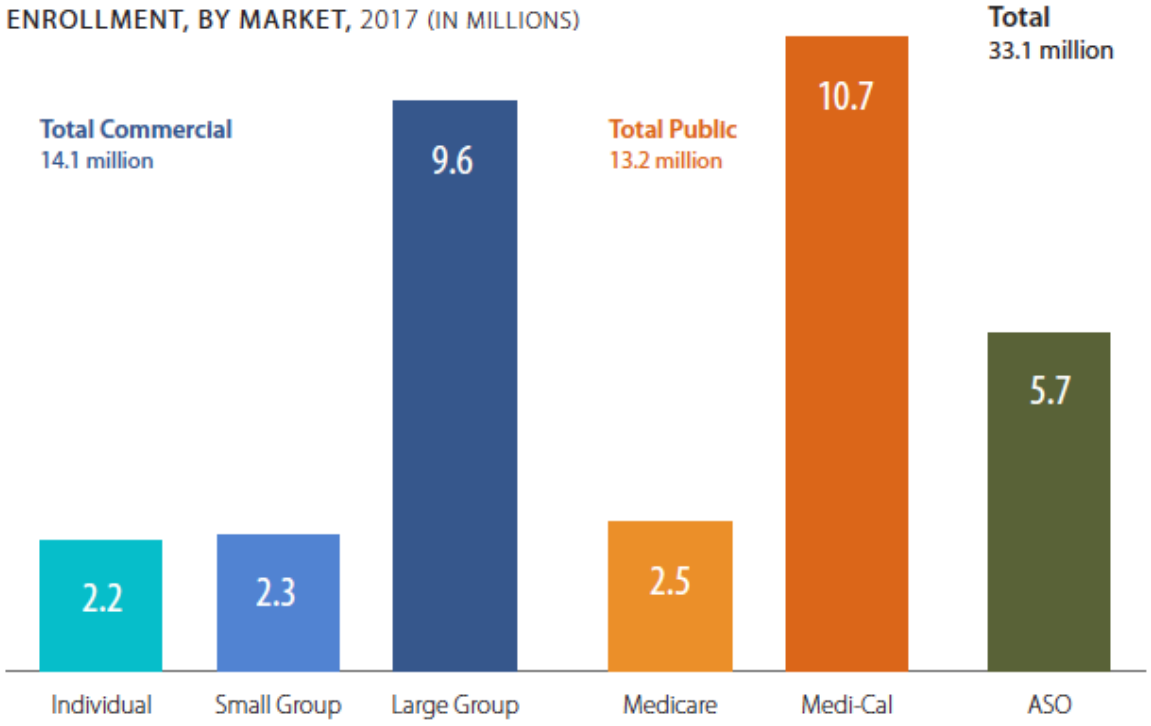
Overview

- Public arousal on high drug prices and spending
- Insurer incentives focused on patients
- Insurer incentives focused on physicians
- Physician organization programs for biosimilars

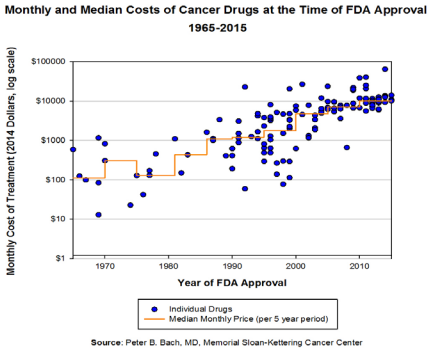
The Landscape: Employer-based, Public, and Individually-Purchased Coverage in California, 2018

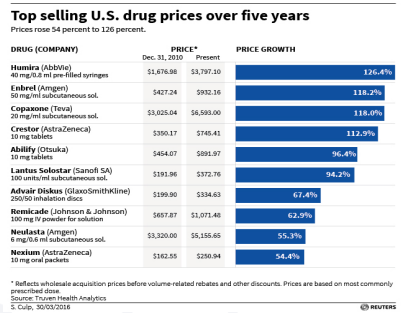


Source: California Healthcare Foundation 2019

Insurer and Policymaker Arousal

- Payers, policymakers, and the public are very aroused on drug prices; the industry is demonized
- Drug trends are a combination of falling spending on retail drugs (due to generic substitution) and rising spending for biologics and specialty drugs (due to new product innovation).
- Per-patient prices for biologics and specialty drugs are rising rapidly at launch and in post-launch increases, and are being passed on thru premiums and cost sharing





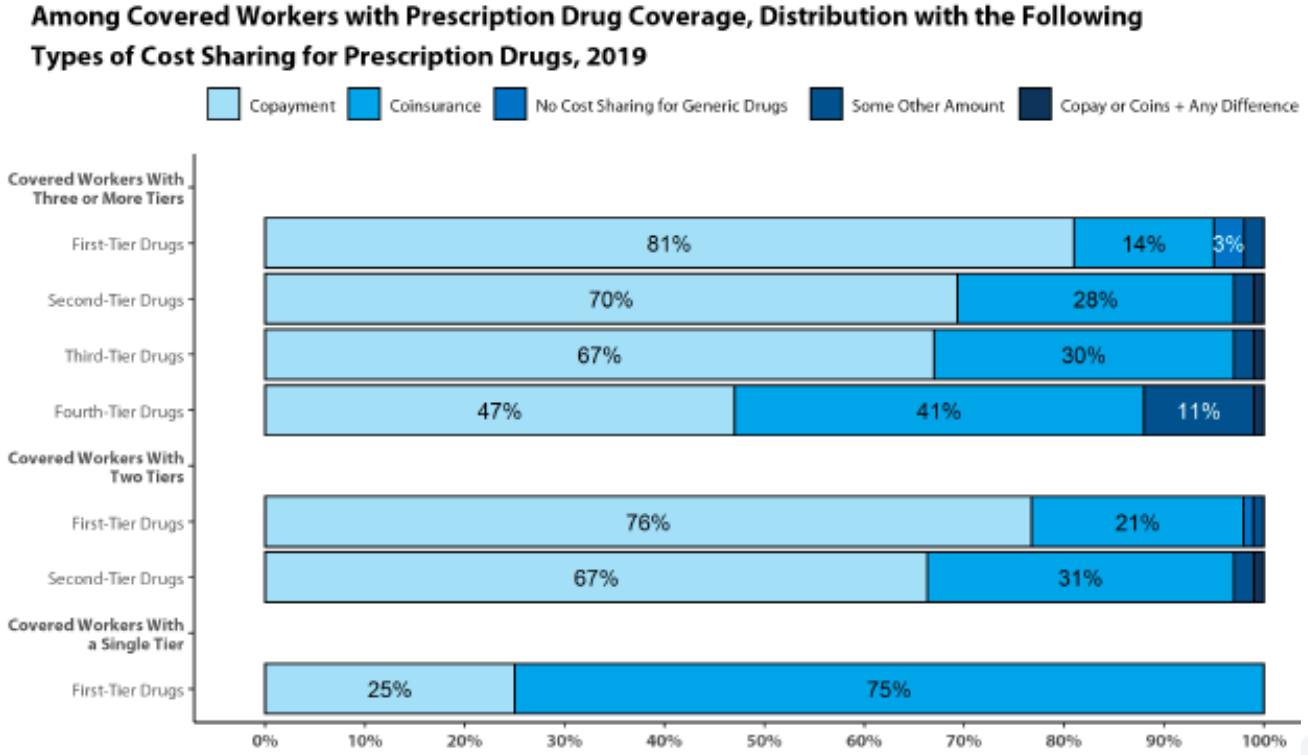
Insurers Currently Focus on Incentives for Patients

- Drug manufacturers in the US are free to set their list prices and insurers (Pharmacy Benefit Managers) are free to negotiate discounts
- Insurers only have bargaining leverage in drug classes where they have a credible threat to shift market share
- To date, their principal focus has been on shifting market share using incentives for patients, as distinct for physicians
- This is changing with the rising importance of biologics and specialty drugs, which are complex and less amenable to patient choice

Insurer Initiatives: Cost Sharing

- The advent of generics led insurers to develop ‘tiered formularies’ (positive lists) where the amount paid by the patient was aligned with the prices charged
  - Tier one with low cost sharing: generics
  - Tier two with moderate cost sharing: discounted brands
  - Tier three with higher cost sharing: non-discounted brands
- They have added a fourth tier for specialty drugs, with percentage coinsurance
- Cost sharing for generics has been very successful (90% penetration) but for specialty drugs imposes severe financial burdens and leads to failures in adherence

Patients Face Ever-Higher Copayments and Coinsurance



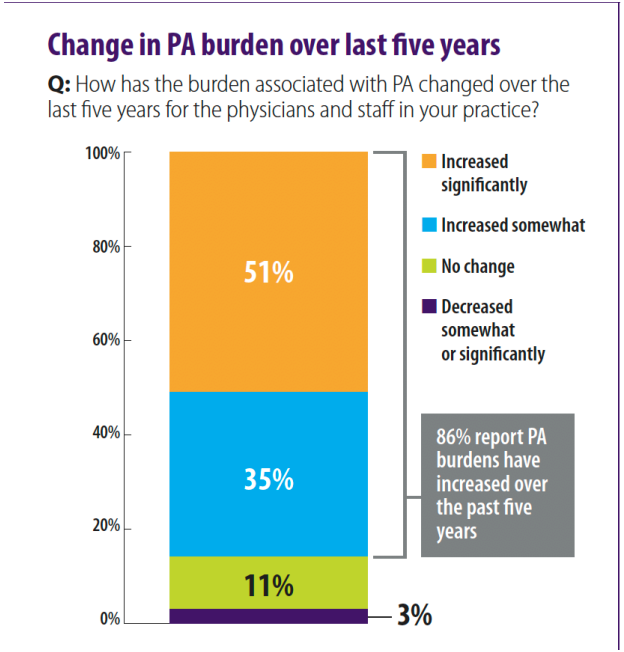
Kaiser Family Foundation: 2019 Employer Health Benefits

Insurer Initiatives: Utilization Control

- For expensive specialty drugs, consumer incentives are ineffective except to engender failures of adherence
- Insurers have strengthened requirements on physicians that limit prescriptions to what they consider to be appropriate patients, and to increase leverage with manufacturers
- Step therapy requires physicians first to prescribe the cheaper alternative before moving to an expensive drug
- Prior authorization requires physicians to document that the patient has the appropriate diagnosis, treatment history, etc.
- Both are burdensome on physicians, and lead to significant reductions in prescriptions

Increasing Stringent Insurer Requirements for Prior Authorization and Step Therapy

- Tighter and more stringent criteria for prior authorization
- Criteria increasingly linked to disease severity, going 'inside the FDA label'
- Requirement for documentation, not merely MD attestation
- More stringent step therapy, with more patients required to 'try and fail' drugs



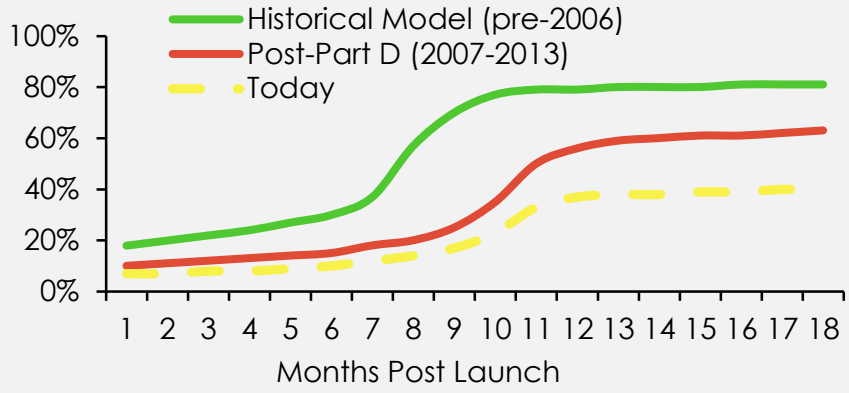
Source: 2017 AMA Prior Authorization Physician Survey

Use of Patient and Physician Incentives to Leverage Price Rebates from Manufacturers

- Insurers use their patient cost sharing and physician utilization management incentives as leverage with drug manufacturers
- In exchange for a reduction in cost sharing or prior authorization by the insurer, the manufacturer must offer a price discount or rebate
- Use of these incentives has been very effective in reducing net prices for drugs facing therapeutic competition, but have come at the cost of severe administrative burdens on physicians and financial burdens on patients

Intense Prior Authorization and Cost Sharing Are Slowing Drug Adoption, Relative to Projections

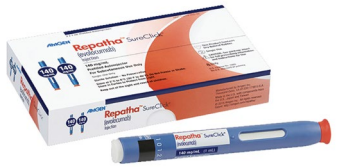
Percent of Potential Post-Launch Adoption Actually Achieved, With Changing Intensity of Payer Management



‡ *Source: QuintilesIMS,* Payer and Managed Care Insights

Example: Price Reduction in Exchange for Lower Patient Cost Sharing

- Amgen Makes Repatha® (Evolocumab) Available In The US At A 60 Percent Reduced List Price
- **New Option Will Lower Out-of-Pocket Costs for America's Seniors at Risk for Heart Attacks and Strokes**THOUSAND OAKS, Calif., Oct. 24, 2018 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that it is making Repatha® (evolocumab), an innovative biologic medicine for people with high cholesterol who are at risk for heart attacks and strokes, available at a reduced list price of $5,850 per year. This 60 percent reduction from the medicine's original list price will improve affordability by lowering patier copays, especially for Medicare patients.



Example: Price Reduction in Exchange for Less Physician Prescription Control (Prior Authorization)

BUSINESS | HEALTH CARE

Regeneron and Sanofi Plan to Cut Cholesterol Drug Price in Exchange for Wider Coverage

They seek to offer rebates and discounts for Praluent and want insurers to ease restrictions on some patients

A cost-effectiveness analysis by an independent group incorporated new clinical trial data showing that Praluent reduced the risk of death. PHOTO: SANOFI AND REGENERON PHARMACEUTICALS/ASSOCIATED PRESS

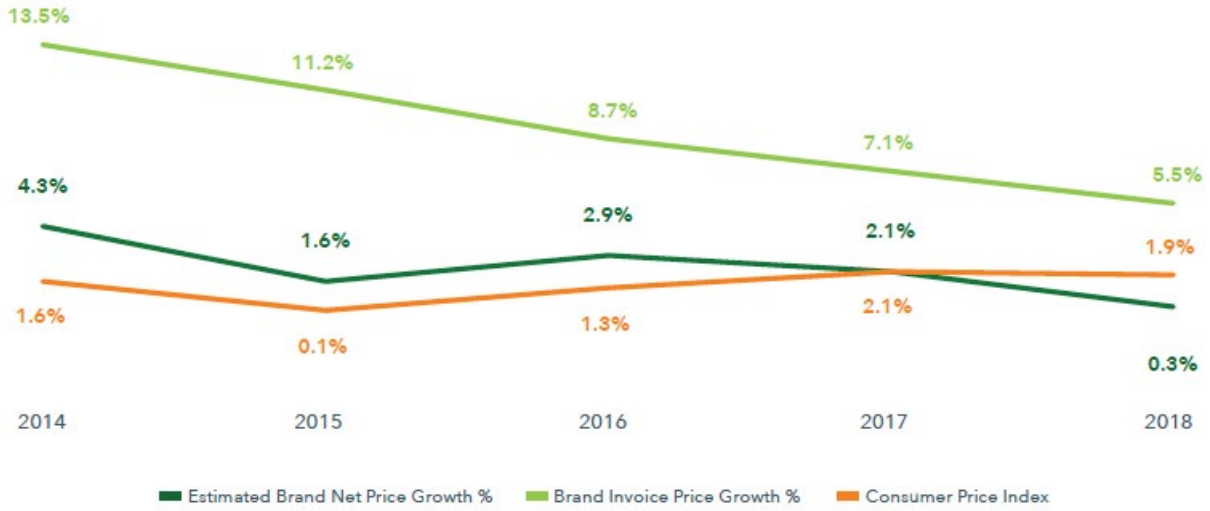
By Joseph Walker

March 10, 2018 9:00 a.m. ET

Negotiations Now Are Reducing Growth in Net Prices, in Some Case to Negative

Protected brand net price increases moderated to 0.3% on average in 2018 as invoice price growth continued to fall

Exhibit 18: Protected Brand Invoice and Net Price Growth %



Source: IQVIA National Sales Perspectives, Jan 2019; IQVIA Institute, Apr 2019

Further Reading

JAMA, June 5, 2018

VIEWPOINT

Value-Based Pricing and Patient Access for Specialty Drugs

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Insurers, employers, and pharmacy benefit managers (PBMs) bemoan high prices for specialty drugs and respond by closely managing patient access to drugs through prior authorization, step therapy, and consumer cost sharing. Pharmaceutical firms are concerned when the use and sale of specific drugs fall short of projections. High prices and access barriers compound each other. Pharmaceutical firms help physicians to navigate utilization management and patients to cover their financial obligations, but then must consider the costs of these programs in subsequent prices. Payers respond to price increases by intensifying access management. Physicians and patients are caught between payers and manufacturers, facing ever-higher administrative and financial obstacles.

The list prices charged for specialty drugs have been rising rapidly in the past decade, both at the time of initial market launch and through post-launch increases.[1] Between 2005 and 2013, for example, the launch price of new oncology drugs increased 12% per year without commensurate increases in efficacy, implying that the price per life-year gained increased from $139 000 to

been interrupted. When poorly designed and implemented, step therapy programs may also make it difficult for physicians and patients to avoid having to start again with therapies that patients have already "tried and failed" before (eg, when enrolled in a different health plan). Some health insurance plans feature annual deductibles and percentage co-insurance instead of dollar co-payments. These have created meaningful financial barriers to specialty drug access. In 2016, 23% of individuals with employment-based insurance had an annual deductible of $2000 or more[5] and 48% of Medicare Part D enrollees were subject to percentage co-insurance for specialty drugs.[6]

The concerns of insurers, manufacturers, physicians, and patients highlight the failure of the current model of drug pricing and access in the United States. Innovative purchasers and manufacturers are potentially interested in closer and longer-term relationships that support the need of the purchasers for affordability and the need of the manufacturers for patient access and net revenue. This requires a new framework for linking price negotiations with improved patient access.

Insurer Initiatives For Physician Organizations

- Insurers recognize that top-down and punitive initiatives (prior authorization, cost sharing) have limited efficacy and arouse substantial resistance for specialty drugs
- They are experimenting with bottoms-up and positive initiatives that engage physician organizations to help manage the use and leverage price reductions for expensive drugs
- Many of these focus on infused biologics, as they are part of the ‘medical’ as distinct from ‘pharmacy’ insurance design, and are delegated to physician organizations

Value-Based Physician Payment Methods Create Incentives to Prescribe Lower-Cost Oncology Drugs

- Some payers are offering oncologists a monthly per-patient fee, as supplement to office visit FFS
    - Care planning and shared decision making, drug management, patient education and monitoring, coordination with other providers
    - Oncologists adhere to approved (lower-cost) drug pathways
- Some payers are offering bonus (shared savings) if oncologists reduce total spending below target
    - Reward for reduced spending on drugs, ED visits, hospitalization
    - Practices must perform well on quality metrics to obtain bonus

Example of Private Insurer: Anthem Blue Cross

- Anthem Blue Cross Blue Shield has a three part payment method for oncology that builds on but extends their existing methods
- focuses on physician adherence to published clinical pathways in oncology
    1. Doctors are paid FFS for patient visits and are reimbursed costs for infused drugs purchased by the practice
    2. Doctors are paid a care management fee of $350/patient/month over and above FFS, if they submit to Anthem clinical and demographic data on each patient, select one of Anthem-developed clinical pathways, and remains adherent to it for 80% of drugs used
    3. They are eligible for an annual bonus if they lower total spending per cancer patient below target.
- Savings are expected to derive from fewer ED visits and lower drug costs

Example of Public Insurer: Medicare

- Medicare 'Oncology Care Model' combines monthly care management fee with shared savings bonus
- They are not at risk (capitated) for expensive drugs, but provided funds to manage care and share in savings (from reduced drug spending)
    1. Doctors are paid FFS for patient visits and cost reimbursement for office-infused drugs
    2. Doctors are paid an additional $160/month for 6 months for patients in active treatment if they comply with 'meaningful use' of electronic medical records, clinician accessible 24/7, patient 'navigation' services, and develop a written care plan for every patient
    3. Doctors are eligible for annual shared savings based on the difference between actual and expected expenditures on physician, drug, hospital, and all other services

Further Reading

Milbank Quarterly 2017:95(1)

THE MILBANK QUARTERLY
A MULTIDISCIPLINARY JOURNAL OF POPULATION HEALTH AND HEALTH POLICY

Original Investigation

Value-Based Physician Payment in Oncology: Public and Private Insurer Initiatives

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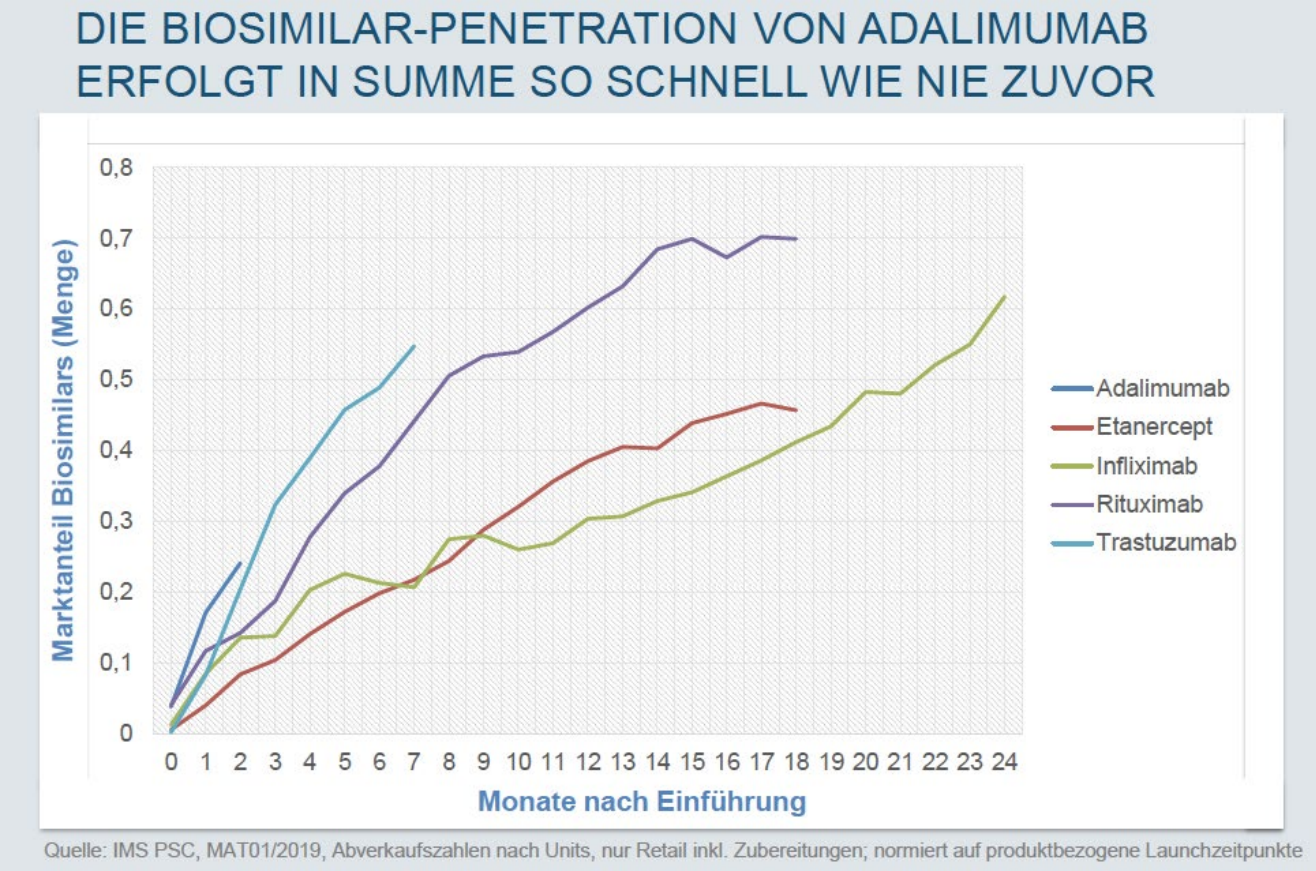
Policy Points:

- Public and private insurers are implementing payment mechanisms to improve coordination and reduce the cost of drug, hospital, and ancillary services for cancer patients. Some target unnecessary hospitalization, while others create incentives for prescribing lower-cost chemotherapies and biologics.
- Physician payment methods in oncology require a balance between incentives for cost control and incentives for patient access to expensive specialty drugs.
- None of the initiatives adopt bundled methods out of concern for shifting excessive financial risk onto physicians in the context of rapid pharmaceutical innovation.

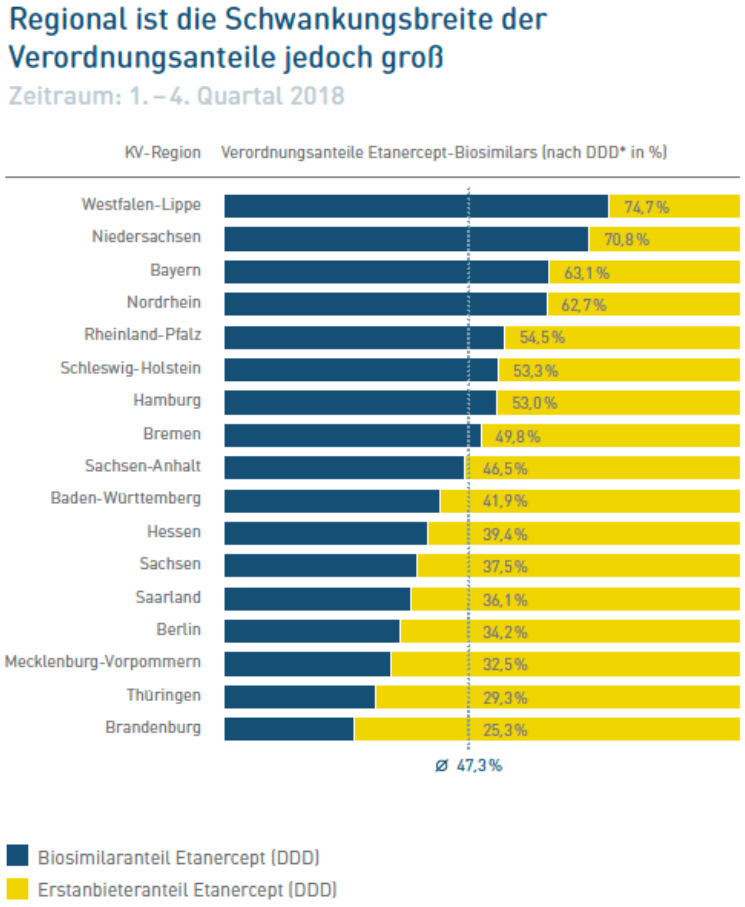
Future Possible Initiatives for Physician Organizations

- In principle, physician organizations are better placed than are insurers to ensure appropriate use of expensive drugs and to leverage price discounts in exchange for higher sales volume
- This is particularly true for biologics and biosimilars, as they are more complex and therefore consumer choice and cost sharing are ineffective
- To date, only a few leading US physician organizations have embraced the opportunity to promote biosimilar prescription as a path to cost savings, but the potential is large

The Potential Rapid Spread of Biosimilars Market Share, Example from Germany



But Uptake Varies According to Engagement by Physician Organizations: Example from Germany



ProBiosimilars: Biosimilars in Zahlen 2018

Selected Physician Organization Initiatives to Promote Biosimilars in the US

- Kaiser Permanente (vertically integrated health plan and physician organization in California): Physician specialty committees assess published evidence on biosimilars. If they feel substitution is feasible, the whole organization shifts (100% biosimilar).
- Articularis Health Group (largest rheumatologist group in US) has moved majority of infliximab patients to biosimilars
- One Oncology (network of 4 large practices in 100 locations): early adoption of biosimilars for Avastin and Herceptin
- Hill Physicians (large primary care and multispecialty network in CA): Bundled payment for care of patients with breast, lung, or prostate cancer that includes cost of drugs as well as physician services (visits, patient education and monitoring), adherence to clinical guidelines.

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