



Talking the  
**TALK**

In the World of Value-Based Care,  
Words Matter

**A LEXICON FOR VALUE-BASED PURCHASING**

## EXECUTIVE SUMMARY

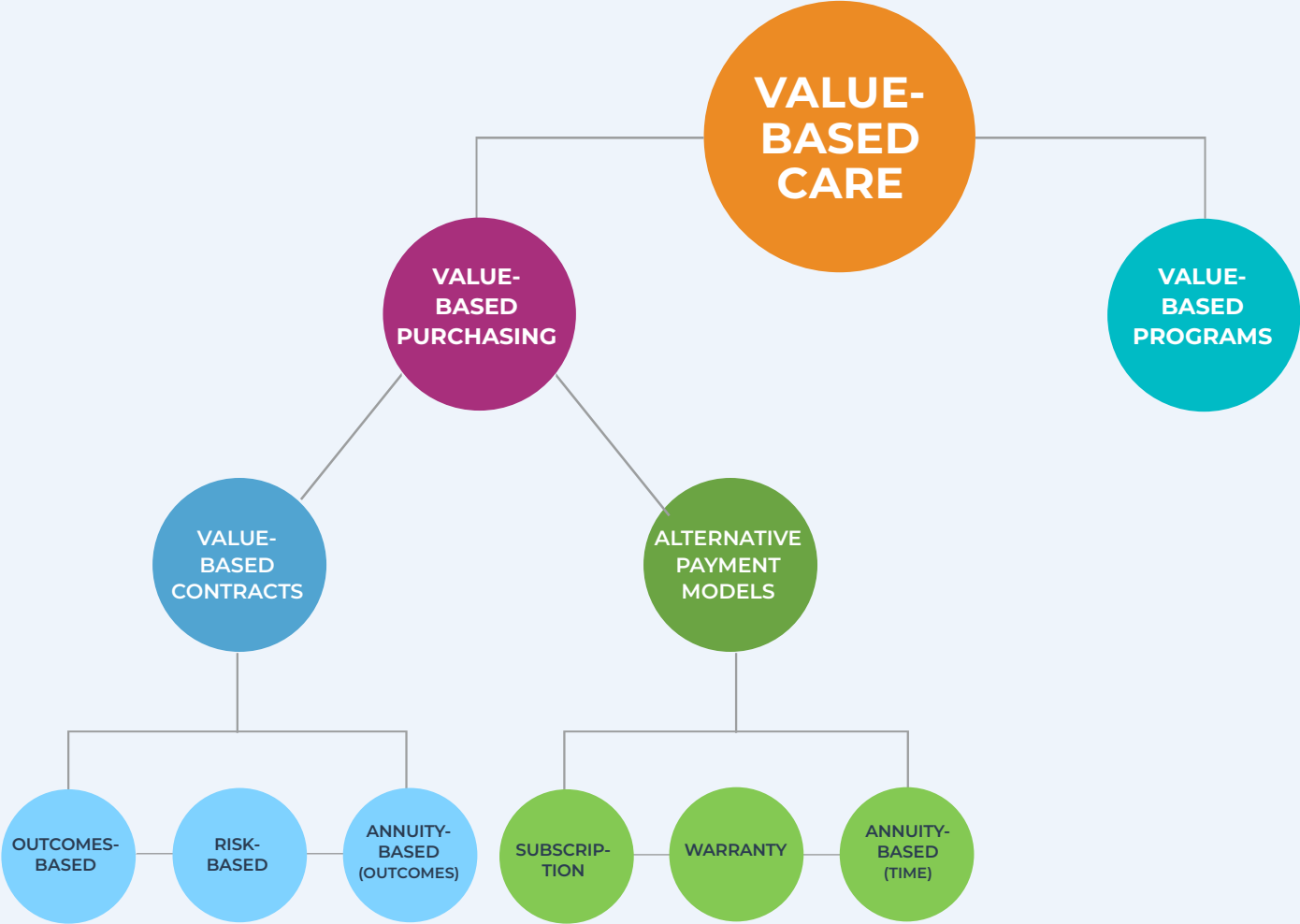
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The evolving health care landscape brings forth innovations not only for vaccines, treatments, and gene therapies but also for the delivery of care and the payment of these medications. Adopting value-based care and alternative payment models offers one important, market-based solution to manage health care affordability, incentivize value, align risk and payment terms, and facilitate patient access.<sup>1</sup> Value-based purchasing agreements are increasingly common, as nearly one in two health plans entered into at least one agreement in recent years.<sup>2</sup> Despite these advances, only one in every three discussions progresses to final contract negotiation and implementation due to many barriers related to regulatory obstacles, data challenges, and organizational readiness.<sup>3</sup> In addition, disconnection, misalignment, and the need to build trust across stakeholders negotiating contractual terms are challenges that are exacerbated by the absence of a common framework for discussion and design of value-based purchasing agreements and alternative payment models.<sup>4</sup> Conversely, achieving agreement on value-based terminology can mitigate these barriers and expedite shared understanding across stakeholders negotiating contractual terms. A lexicon is foundational for all stakeholders to engage and advance value-based care initiatives using a unified language.

In 2021, the Academy of Managed Care Pharmacy (AMCP) convened an advisory group of 21 value-based care experts from integrated delivery networks, health plans, pharmacy benefit managers, biopharmaceutical manufacturers, and consulting organizations to identify and address barriers to value-based care. The first goal of the advisory group was to create and circulate a lexicon inclusive of terminology and definitions and establish a common framework for stakeholders engaging in value-based care models. The advisory group commissioned a literature search, and data analysts applied natural language processing analytics to identify and create standardized definitions for value-based care. After assessing the frequency and correlations of terms, these were then refined in a two-part process with the advisory group and voted upon to identify the final definitions for the value-based care and alternative payments outlined in this white paper. Final definitions were then organized into a hierarchical framework. *(Figure 1)*

This document includes the resulting definitions, examples of real-world applications, and a summary of the methodology that led to the lexicon development. Ultimately, this lexicon is recommended as a tool for groups engaging in value-based purchasing contracts. Sharing the same lexicon across provider groups, payers, and manufacturers can facilitate faster alignment among all involved parties' value-based care goals and objectives.

FIGURE 1. LEXICON HIERARCHICAL FRAMEWORK



## Lexicon of Value-Based Purchasing Terms

Value-based care centers on the core objective of aligning risk through contractual terms by tying reimbursement to the product's performance or achievement of health, real-world, or economic outcomes.

While not specifically included as a value-based contract, other alternative payment contracts seek to add to the

predictability of total costs, health, or other real-world or economic measures. Advisory group members recognized that value-based contracts vary depending on many factors such as the treatment product characteristics, the durability of treatment response, place in therapy or setting of care, the length of the agreement, and stakeholders involved.

Value-based care can be delineated between initiatives tied to a financial contract for a product, or "value-based purchasing," and initiatives that involve rewarding health care providers based on the quality of care delivered, or "value-based programs." (Figure 2)



### Value-based care:

A health care delivery model that reimburses for provider or therapy performance by expected or measured patient health metrics, real-world outcomes, or costs over a defined period of time.



### Value-based purchasing:

An adjusted payment for a medical intervention or a manufacturer product that meets pre-determined metrics or payment milestones; the agreement aims to enhance the quality of care by rewarding decisions that improve patient health measures or other real-world outcomes.

### Value-based program:

A program that facilitates quality care by awarding incentive payments to providers that deliver evidence-based treatment decisions which drive better care for individuals, improved health for populations, lower costs, or more efficient provider workflows.



FIGURE 2. VALUE-BASED CARE



Value-based purchasing was then further segmented to delineate between performance-based contractual agreements, or “value-based contracts” and contractual arrangements that do not typically measure the performance of the product, such as “alternative payment contracts” or “alternative payment models.” In today’s environment, some contracts have evolved from bilateral agreements between two stakeholders to multilateral agreements to align incentives among health plans, pharmacy benefit managers, provider networks, and biopharmaceutical manufacturers.<sup>4</sup> (Figure 3)



**Value-based contract:**

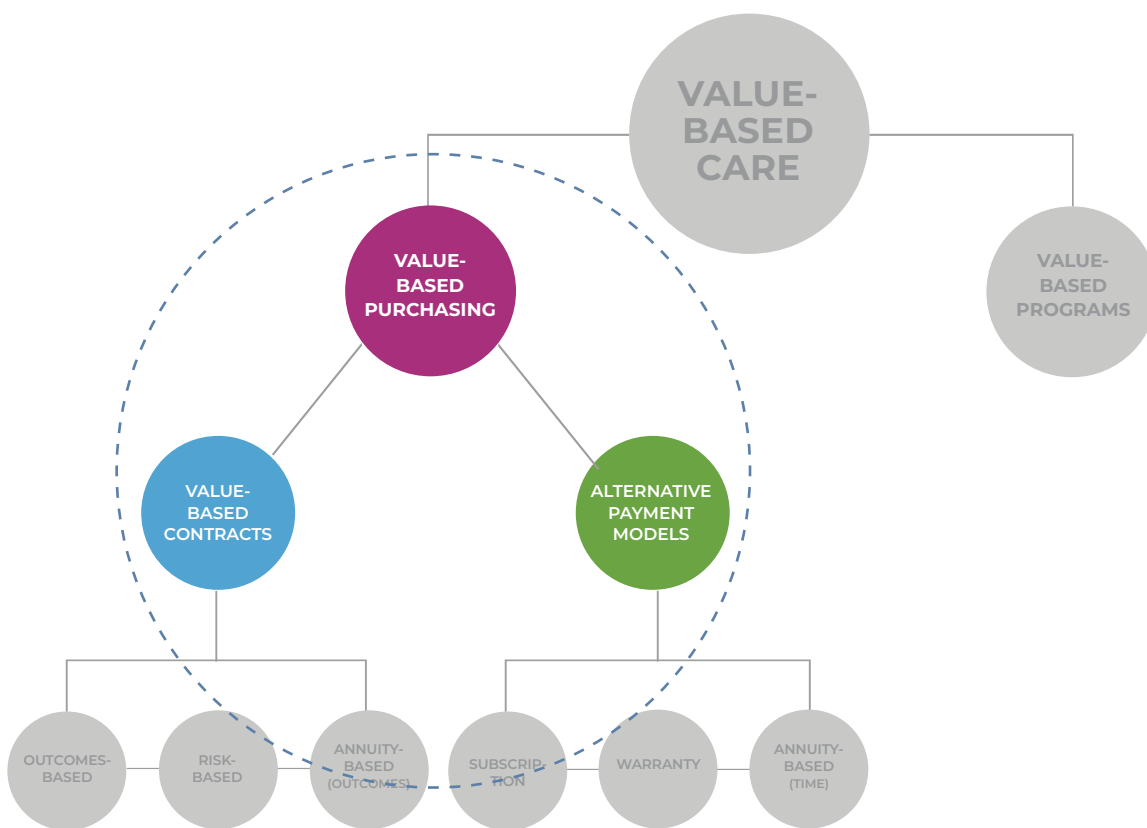
A performance-based contract among payer, provider, and/or manufacturer stakeholders in which reimbursement is tied to patient health measures or other real-world outcomes and costs for a defined period of time.

**Alternative payment models:**

A payment approach centered on providing predictable costs that ties payment to provider or therapy performance over a defined period of time.



FIGURE 3. VALUE-BASED PURCHASING



## A Closer Look at Value-Based Contracts

Value-based contracts can be designed on three premises (Figure 4):

- Whether outcomes are measured (*outcomes-based contracts*).
- If risk for achieving patient, clinical, or economic metrics is shared between contractual stakeholders (*risk-based contracts*).
- If payments are made over time based on whether outcome metrics are achieved (*annuity-based contract, outcomes*).



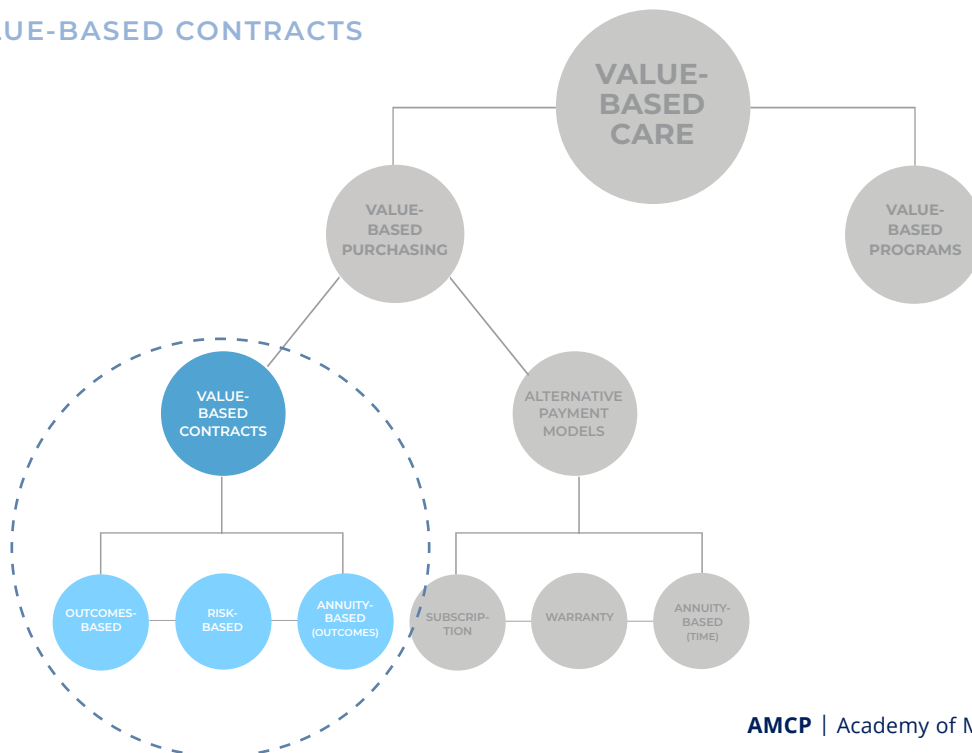
### Outcomes-based contract:

A contract between a payer, manufacturer, and/or health care provider that links payment for a treatment that meets, exceeds, or fails to meet expected patient health measures or other real-world outcomes over a defined period of time.

**Outcomes-based contracts** can involve two or more stakeholders to facilitate care coordination, data collection, and outcome measurement. For example, providers may need additional training or to collect unique health data for rare or orphan diseases and contractual purposes. These contracts may include financial bonuses if metrics are met (or exceeded) or rebates if metrics are not achieved.

While applicable to all disease states, outcomes-based contracts typically include clinical outcomes captured in routine patient care (e.g., lab results, dose intensification, treatment changes) or collected through claims data

FIGURE 4. VALUE-BASED CONTRACTS



(e.g., transfusions or hospitalizations). Additional challenges exist for rare and orphan conditions if there are insufficient patient populations to evaluate outcomes or address variation in treatment response across patients. Further, tracking outcomes requires participating stakeholders to have sufficient data, analytic capabilities, and staff resources to clean and report findings.



### REAL-WORLD EXAMPLE

An example of an **outcomes-based contract** is the arrangement between multiple commercial health plans and Spark Therapeutics (Spark) for LUXTURNA® (voretigene neparvovec-rzyl), a one-time gene therapy indicated for certain subtypes of retinal dystrophy. In this agreement, Spark shares risk with health insurers by paying rebates if patient outcomes (after establishing a baseline level) fail to meet a specified full-field light sensitivity threshold, thereby linking the payment to both short-term efficacy (e.g., 30–90 days) and longer-term treatment durability (e.g., 30 months).<sup>5</sup>

### Risk-based contract:

A contract that links reimbursement to the distribution of risk of a medical intervention or a manufactured product by measuring performance over a defined period of time.



**Risk-based contracts** link payment to the distribution of risk for the specified treatment or medical intervention, which can be done by measuring financial performance, medication utilization, or health outcomes. Similar to outcomes-based contracts, risk-based contracts are advantageous when treatment outcomes are uncertain (such as the durability of CAR T-cell or gene therapy) or hard to measure. The key difference is that risk-based contracts have a greater focus on financial performance. In addition, risk-based contracts are defined by their reliance on expected real-world outcomes and the assumption that treatment responses may vary. Finally, risk-based contracts may include upside (e.g., potential supplemental payment if predefined metrics or savings are achieved) or downside risk (e.g., penalties if metrics are not met).



### REAL-WORLD EXAMPLE

For example, a **risk-based contract** is the arrangement proposed by Alnylam for GIVLAARI™ (givosiran), its RNAi therapeutic used to treat acute hepatic porphyria, a disease affecting the nervous system. In these arrangements, commercial payers would pay the full value for givosiran if patient outcomes in the real world are similar to results demonstrated in clinical trials.<sup>6</sup>



**Annuity-based contracts with outcomes:**

A multi-year agreement that ties reimbursement installments for a medical intervention or manufactured product to pre-determined outcomes or cost measures over a defined period of time.

**Annuity-based contracts** are centralized around a pay over time approach that allows payments to be made in installments. While some contracts may be based purely on payment installments, **annuity-based contracts with outcomes** include additional metrics that link reimbursement to clinical performance.



**REAL-WORLD EXAMPLE**

While few annuity-based contracts are publicly disclosed in the US, an example of an **annuity-based contract with outcomes** is a payment model in Europe arranged by GlaxoSmithKline<sup>✦</sup> for STRIMVELIS<sup>®</sup>, an autologous CD34+, for severe combined immunodeficiency due to adenosine deaminase deficiency. As a one-dose therapy, payments are made over time with reduced payment if pre-determined outcome measures are not met.<sup>7</sup>

<sup>✦</sup> STRIMVELIS<sup>®</sup> was divested by GSK to Orchard Therapeutics in 2018.

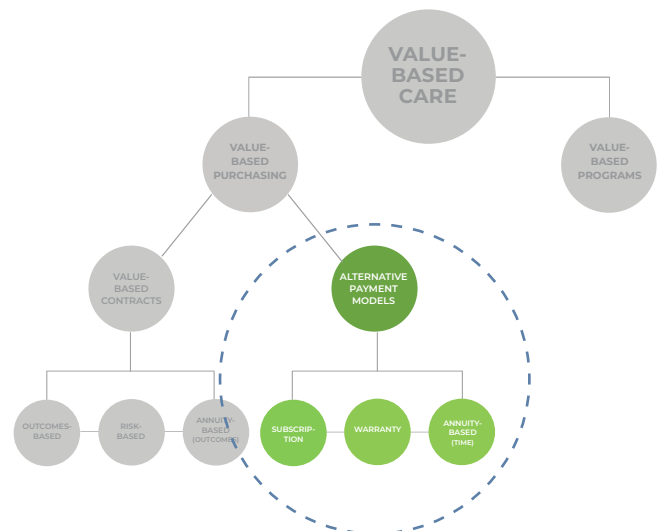
**A Closer Look at Alternative Payment Models**

In contrast to value-based contracts, alternative payment models (APMs) are based on methods of payment not based solely on improved health outcomes. While these arrangements are designed in ways that can enhance care value (e.g., by improving patient and system affordability of therapies with high demonstrated value, or by providing reimbursement when outcomes are not achieved at an individual patient level), they are distinguished from strictly outcomes-based or “value-based contracts” for purposes of this lexicon. Variations of alternative payment models can be delineated based on whether the agreement includes:

- A set fee for all patients or a defined level of utilization or dose (*subscription model*).
- Guaranteed reimbursement or remediation for negative financial or health outcomes (*warranty models*).

- Payments over time (*annuity-based models, time*) (Figure 5).

**FIGURE 5. ALTERNATIVE PAYMENT MODELS**







### Subscription models:

A payment model that provides a medical intervention or a manufactured product for a set fee to treat a certain proportion of patients or a set price per patient.

**Subscription models**, sometimes referred to as “Netflix” or expenditure cap models, limit the cost to treat a patient or patient population to a certain negotiated total cost (e.g., a price per patient treated or a set fee regardless of the dosage or units of product). This cap can also be triggered when a utilization threshold is reached at either a patient or plan level. Subscription models may include only a single therapy or multiple therapies for a condition.



#### REAL-WORLD EXAMPLE

An example of a **subscription model** is the state of Louisiana’s payment model for hepatitis C drugs, Epclusa® (sofosbuvir/velpatasvir), in which the manufacturer, Gilead Sciences, agreed to provide access to patients enrolled in Medicaid or incarcerated in exchange for a fixed amount of money over five years.<sup>8</sup>

### Warranty models:

A policy, typically through a third-party administrator, that reimburses treatment-related costs for suboptimal performance.

**Warranty models** offer a guarantee of reimbursement from the biopharmaceutical manufacturer to cover additional treatment-related costs that arise from suboptimal product performance. Some warranty models may refund the cost of treatment and/or ancillary care. In addition, some warranties or guarantees may refund payers as well as reimburse patients for out-of-pocket costs. The warranty model may reduce regulatory concerns (e.g., Anti-kickback Statute and Stark Law) and mitigate financial risk and data collection obligations required by outcomes-based contracts.



#### REAL-WORLD EXAMPLE

An example warranty model is Pfizer’s Pledge Warranty Program for adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) starting PANZYGA. For eligible patients, Pfizer will refund drug costs up to the first four treatments if discontinued by the provider for clinical reasons, up to a defined maximum dollar amount. Administered by a third-party claims administrator, refunds prioritize any patient out-of-pocket drug costs incurred; the maximum refund limit minus patient spending will be refunded to commercial insurance. The program is available to cash-paying or commercially insured patients; and not those who are covered by Medicare nor any other public program.<sup>9</sup>



### **Annuity-based models:**

A multi-year contract model that spreads reimbursement installments for manufactured products over time.

**Annuity-based models**, like annuity-based contracts based on outcomes, make periodic payments. However, annuity-based models do not necessarily require measurement of health outcomes. Annuity-based models commonly spread costs over multiple years and may be especially advantageous for plans with lower financial risk tolerance or when treatments have high up-front costs, such as cell and gene therapies.



### **REAL-WORLD EXAMPLE**

An example of an **annuity-based model**, which is a payment-over-time approach, is offered for ZOLGENSMA® (onasemnogene abeparvovec), a one-time treatment for children with spinal muscular atrophy. The approach offered by Avexis in partnership with Accredo allows installment payments for up to five years.<sup>10</sup>



A primary objective of the AMCP Advisory Group to Address Barriers in Value-based Care was to facilitate standardization of the lexicon used to describe payment models commonly leveraged in value-based care. Creating a common language that can be used regardless of context or stakeholder can unify terminology and align the dialogue among parties when discussing value-based care strategies.

Value-based contracts continue to change in light of innovative pharmaceutical therapies, care delivery, financial tools, and updated regulatory guidance. Therefore, the advisory group recognizes the lexicon can and will evolve. As an initial action step, facilitating the adoption of a unified lexicon may help mitigate areas of confusion and set a foundation on which to collaboratively discuss and ultimately design value-based payment arrangements.

## About the Methodology

In 2021, the Academy of Managed Care Pharmacy (AMCP) convened an advisory group of 21 value-based care experts from integrated delivery networks, health plans, pharmacy benefit managers, biopharmaceutical manufacturers, and consulting organizations to identify and address barriers to adopting value-based care. The first goal of the advisory group was to create and circulate a lexicon inclusive of terminology and definitions to establish a common framework vocabulary for stakeholders engaging in value-based care models.

The advisory group commissioned data analysts to apply natural language processing analytics on bodies of text to derive foundational insights for creating standardized definitions. The first step in this process was to perform a literature search to identify the most common words, phrases, and definitions associated with value-based care language.

A literature search was performed to identify the most common words, phrases, and definitions associated with value-based care. Criteria for the literature review were:

- Published after September of 2016.
- Published in peer-reviewed journals or public domain information.
- Search terms included: value-based contract, value-based arrangement, outcomes-based contract, annuity-based contract, annuity outcomes contract, risk-based contract, indication-based contract, regimen-based contract, value-based health care, value-based care, value-based programs, value-based collaborations, value-based enterprise, value-based payment, value-based purchasing, innovative contract, performance-based contracting, milestones-based contracting, subscription model.

The resulting 178 articles (*references available upon request*) were a combination of peer-reviewed literature and policy documents for stakeholders and government releases. The goal of collecting a large sample of articles was to capture themes, relationships, and meaning behind the target phrases and their current real-world application. The researchers applied natural language processing software to identify search terms within each document. Variations of a word were standardized to a single tense to capture the root word. Similarly, synonyms were refined and standardized to a single tense.

Each document was separated by paragraph. Target terms or phrases were required to appear in at least ten paragraphs across the documents. Terms or phrases that appeared in less than ten paragraphs were deemed to have an insufficient sample size and were excluded from further analysis. Once the inputs were processed and cleaned, a term-document matrix was developed to assess the correlation levels and relationships between different words and phrases. These correlations gave insight into which words or phrases were commonly used in sentences or paragraphs together, suggesting possible relationships between those words or phrases. Correlations greater than 0.25 were considered significant and assisted in generating formal, unified term definitions.

To test the validity of the quantitatively established foundation, advisory members gathered and analyzed common definitions from reputable literature and matched those definitions with highly correlated terms from the term-document matrix. Public information from AMCP, the Centers for Medicare and Medicaid Services (CMS), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the *New England Journal of Medicine (NEJM)* were also contributed. Ultimately, definitions were refined to align language with current use

and crosschecked with highly correlated terms. The advisory group also incorporated results from previous attempts to gain consensus on value-based care terminology.<sup>11</sup> Finally, definitions underwent review by a regulatory expert to compare terms with codified terminology.

In 2023, an update was made to include current examples of value-based care. AI-powered search engines and language models (ChatGPT, BING, and Bard) were leveraged to conduct research and to generate lists of articles published in the last 24 months on value-based care in order to identify current examples of value-based purchasing models. Identified examples were validated by literature review and analysis.

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## Advisory Group Members\*

\* We thank and acknowledge the following individuals who participated in the AMCP Advisory Group. The content of the paper does not represent the views of any particular member and the Advisory Group did not have editorial control of the content. Engagement in this Advisory Group should not imply endorsement by the participant's respective organization.

**Alison LaPibus**, Director, Policy and Research, PhRMA

**Amanda Gordon**, Pharm D, MS, Vice President, Ambulatory Pharmacy, Bon Secours Mercy Health

**C. Bernie Good**, Senior Medical Director, UPMC Health Plan Insurance Services Division

**Chase Michael Byerly**, Senior Director, Value Excellence, Lilly

**Christina Barrington, PharmD**, Vice President, Chief Pharmacy Officer, Priority Health

**Dorothy Hoffman**, Head of Global Immunology Policy, Novartis

**Jane F. Barlow, MD, MPH, MBA**, Chief Clinical Officer, Real Endpoints and Senior Advisor, Tufts NEWDIGS

**Jay Newman**, SVP, Commercial Development, Pricing & Reimbursement, Spark Therapeutics

**Jeff Chaffin**, President, Miles Payer Consulting, LLC

**Jessica Daw**, Vice President of Pharmacy, Sentara Health Plans

**James T. Kenney, RPh, MBA**, President, JTKENNEY, LLC

**Kimberly Lenz**, PharmD, MBA, FAMCP, Chief Pharmacy Officer, MassHealth, Office of Clinical Affairs, ForHealth Consulting, UMass Chan Medical School

**Myla Maloney**, Chief Growth Officer, PINC AI Applied Sciences, Premier Inc

**Pat Gleason**, Assistant Vice President, Health Outcomes, Prime Therapeutics

**Stephen George**, PharmD, MS, Senior Consultant, Milliman, Inc.

## AMCP and Valuate Health Consultancy Staff

**Jennifer Mathieu**, Senior Vice President, Professional & Government Affairs, AMCP

**Tom Casey**, Manager, Government Affairs, AMCP

**Lori Wood**, Principal, Valuate Health Consultancy

**Emery Weinstein**, Consultant, Valuate Health Consultancy

**Kimberly Tsai**, Consultant, Valuate Health Consultancy

**Ian Baldwin**, Data Analyst, Valuate Health Consultancy

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