Value Based Health Care - Risk Share Contracts

What is it?

This is a payment arrangement between two parties that involves tracking the performance of an intervention and its impact on patient outcomes. Outcomes are tracked in a defined patient population over a certain period of time and the level of reimbursement is based on the health and cost outcomes achieved. These types of arrangements can be described as value based health care, coverage with evidence, access with evidence development, risk-sharing agreements, outcomes-based agreements, conditional licensing agreements, and sometimes are called patient access arrangements. There are typically two objectives for these types of risk sharing arrangements, one to gain experience for a novel intervention and two, answer the underlying outcome or health economic question that is either preventing market adoption currently or threatens future patient access. Therefore, performance based risk sharing agreements do have a clinical and scientific element that require the rigors of a study protocol that can produce an answer to the patient outcome or health economic question. This type of arrangement is just one mechanism to reduce market access uncertainty through greater investment in evidence collection while still gaining experience using a novel technology.

Why do it?

Elements of a Performance Based Risk Sharing Agreement

1. Data collection agreement between two or more parties to address uncertainties about effectiveness, including complications, thereby reducing uncertainty about the expected cost-effectiveness of an intervention.
2. Most often data collection for performance based risk sharing agreements occurs after regulatory approval, but sometimes before the full uptake of the new health technology. This can occur with full or conditional regulatory approvals, to prove net health outcomes.
3. Price, reimbursement, and/or revenue for the intervention are linked to the outcome of the established study protocol and agreement. This can be negotiated as either explicit coverage during the study period, or by implicit coverage with an option to renegotiate coverage policy. The later only need be done with limiting coverage policies or exemptions based on a specific intervention within a class.
4. Data collection is usually intended to address uncertainty concerning one or more of the following; but this is not an inexhaustible list.
    a. Expected outcomes of the treated population as compared to those obtained with the use of an alternative treatment regime to that in trials or with different combinations or sequencing of new and alternatives therapies; such as in acute ischemic stroke with IV-tPA given within 3 hours of onset, and determining the best alternatives after 3 hours.
    b. The effectiveness or safety in a broader population, one outside of registration trials, or clinical specialty centers.

c. The impact of long-term clinically significant outcomes based endpoints, such as death, complications, and morbidity. Most often these endpoints are not determined in a regulatory approval clinical trial, but must be answered by additional outcomes research.
d. The size and value of cost offsets, such as fewer hospital visits
e. To determine the net health benefits of patient management for a particular disease state under a coordination of care model such as an integrated health care system like Kaiser or Intermountain Health Care or some newer at risk models such as ACOs like Geisinger Health.
f. To determine if the patient population is the "right" population, i.e. they have attributes that the payer can determine based on current evidence will most likely benefit and therefore are willing to fund. The limitation of the current evidence may be from a clinical trial setting, and the payer is interested in determining "real world" outcomes in their population.

Cost Sharing Arrangements

What is it?

These are agreements that are based on price-volume, utilization management, rebate volume discounts, or utilization capping. They are typically not considered VBHC or HEOR arrangements, because they fail to have an underlying patient outcome or health economic research objective.

Why do it?

These are risk-share arrangements purely for commercial gain and are devoid of improving patient outcomes beyond current treatment standards, therefore Da Vinci Health Group does not offer services for this this type of risk-share contract.