



ValidationInstitute

2020 Validation Report

Review for: Care Oncology
Valid through March 2021



Company Profile



Category:	Cancer Management
Website:	https://careoncology.com/
Public or Private:	Private
Year Established:	2014
CEO:	Raphael Swery
Company contact:	support@careoncology.com

Description:

Care Oncology's mission is to act in patients' best interests, by helping them to live longer and healthier lives, and to do so without fear. Many old medicines are potentially useful in new ways. Some of them can and do help in cancer, but modern economic incentives and industrial imperatives make it supremely difficult for the effort needed to enable their use in cancer to happen. Modern medicine has moved forward tremendously, and there have been many exciting breakthroughs in cancer therapy but there is little doubt that many of the new approaches can be helped by the old medicines too. **Care Oncology** believe that patients should get the best of the old and the new.



Claim Assertion for Validation

Breast and prostate cancer patients who take statins and/or metformin tend to have lower rates of death. Since cancer patients' expenses are highest at initial diagnosis and at end-of-life¹, a lower mortality rate can reduce medical costs for payers. In addition, statins have been shown to reduce the five-year breast cancer recurrence rate; having fewer patients experience recurrence would also lower medical costs.

Care Oncology Clinics use a patented combination of low-cost, low side-effect drugs, which have been shown to improve cancer treatment outcomes. The medications are in addition to and do not alter the patient's cancer treatment.

This validation uses previously published research and focuses on two cancers that are common in working-age populations: breast and prostate.

Intervention Link to Outcome

- **State the outcome being measured.**

Mortality of breast and prostate cancer patients, stratifying the patients by whether they are also taking a statin or metformin oral drug during their cancer treatment.

Five-year recurrence of breast cancer, separating patients by whether and what type of statin drug they took.



- **Detail the intervention.**

Patients are prescribed a statin and metformin once they have begun their cancer treatment. The intervention adds to, rather than changes, the cancer treatment. Care Oncology Clinics prescribe a repurposed combination of existing, licensed medications which are used to treat conditions other than cancer. This standard of practice is known as off-label use. Research suggests that these drugs may complement and enhance the effect of traditional, standard-of-care cancer therapies.

- **Does the applicant discuss published literature or other credible source demonstrating correlation between intervention and outcome? If yes, describe the correlation and the source cited by applicant. If no, does the literature exist to demonstrate a correlation between intervention and outcome?**

Yes.





Method / Calculation / Examples

A nationwide cohort study of women with breast cancer stratified women by whether they were taking a statin drug. The breast-cancer-specific mortality rate was compared between the two groups.

A meta-analysis combined data from three studies of recurrence free survival among breast cancer patients, stratified by whether and what type of statin medication they were taking.

A population-based retrospective cohort study merged data from public health data sets on prostate cancer patients. The mortality rate for patients who had taken a statin alone or in combination with metformin was compared to patients who had neither drug.

Data Source

- **Describe the data source.**

The breast cancer study used clinical and administrative records, gathered by the public health system. The meta-analysis used previously published studies.

The prostate cancer study used data from two public data sets – the Surveillance Epidemiology and End Results (SEER) and the Medicare Prescription Drug Event files.



- **Did the applicant have adequate data from a credible, reliable source?**
Yes.
- **How is the data source appropriate for the outcome being measured?**
In all three studies, the data sources are credible and reliable for the measures used.

Methodology

- **Describe the evaluation methodology, i.e. trend from pre- to post-, comparing similar groups, etc.**
All three studies compared a group of patients taking the drugs to a group not taking the drugs during their treatment period. Mortality and recurrence measures were then applied to each group.
- **Did the applicant collect and manage data in accord with standard evaluation methodology? Comment on any issues with compiling the measure, such as missing or incomplete data or lack of data on non-participants.**
Not applicable as this is previously published research.



Findings & Validation

The breast cancer cohort study found that patients taking a statin had a 16% lower rate of breast-cancer-specific death than patients not taking a statin.

The meta-analysis found a 12% lower five-year breast cancer recurrence rate for patients taking lipophilic statins.

The prostate cancer patients who took a statin alone or in combination with metformin had 11% lower rate of death overall, and a 20% lower rate of death from prostate cancer than patients who took neither drug.





Validation and Credibility Guarantee

Care Oncology achieved level 3 validation for Metrics. Validation Institute is confident that **Care Oncology** performs as they state they are willing to provide up to a \$10,000 guarantee as part of their Credibility Guarantee Program*.

Level 1 - Savings

Can produce a reduction of health care spend including the cost of the provider. Product/solution has produced, and replicated a lower cost for healthcare overall or a specific component of healthcare

Level 2 - Outcomes

Product/solution has measurably “moved the needle” on an outcome (risk, hba1c, events, employee retention, etc.) of importance.

Level 3 - Metrics

Claim is made that – with sourced, overridable assumptions linked to peer-reviewed or government sources

Level 4 - Contractual Integrity

No outcomes or savings has been shown, but vendor is willing to put a part of their fees “at risk” as a guarantee





Limitations

Though the impact of the intervention on cancer mortality rate is well established in literature, the impact on a payer's medical costs is not yet demonstrated.





Validation Expiration: March 2021

CERTIFICATE OF VALIDATION

Applicant:	Care Oncology 1122 Jackson Blvd Rapid city, South Dakota, 57702
Product:	Patented combination of low-cost, low side-effect drugs
Claim:	Breast and prostate cancer patients who take statins and/or metformin tend to have lower rates of death
Validation Achieved:	Level 3 – Validated for Metrics

Linda Riddell
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About Validation Institute

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of healthcare.

To strengthen our offering and provide additional credibility around our service, the **Validation Institute** recently announced a Credibility Guarantee* that offers customers of validated solution providers up to a \$25,000 guarantee. This guarantee confirms that a validated solution provider will, achieve what the validation language on a marketing claim says it will achieve.