

MILLIMAN REPORT

# Peer review of OnTrak program savings reconciliation methodology

Commissioned by OnTrak, Inc.

April 2021

Stoddard Davenport, MPH  
Doug Norris, FSA, MAAA, PhD





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## Introduction

This report serves as documentation of Milliman's peer review of the savings reconciliation methodology used by OnTrak to evaluate the financial outcomes of the OnTrak program. This document describes the methodology that we reviewed and the conclusions of our review, as well as some considerations to keep in mind when relying on this type of study design.

## Background and scope

OnTrak, Inc. contracts with health plan partners to offer OnTrak, a 52-week program that engages patients with what OnTrak determines are untreated or undertreated behavioral health conditions in enhanced treatment and care management. OnTrak uses proprietary analytical methods to identify and enroll eligible patients with the goal of improving health and reducing healthcare costs. OnTrak developed a pre-post study design to estimate cost savings from the program. OnTrak engaged Milliman to conduct a peer review of the study design to evaluate the reasonability of OnTrak's approach. This report describes the findings of Milliman's review.

Milliman has peer-reviewed the study methodology developed by OnTrak, but not any specific results or conclusions generated using this methodology. The particular circumstances, limitations, or other criteria for any specific analysis may differ from the prototypical scenario that Milliman reviewed. Milliman's review did not include any health plan partner-specific modifications to the reconciliation methodology, as any such adaptations are outside the scope of our review. Milliman's findings should not be construed as applying to any deviations from the study design that Milliman reviewed (as described within this document). Furthermore, Milliman's review should not be interpreted as providing any sort of endorsement of, or opinion about, the OnTrak program.

## Results

Overall, we found the savings reconciliation methodology employed by OnTrak to be a reasonable execution of a pre-post study design, given the circumstances of its implementation and delivery. This study design is subject to a number of limitations inherent to pre-post study designs, which should be considered alongside any results calculated using this approach. In particular, we note that pre-post study designs may be susceptible to regression to the mean when program eligibility is (at least in part) determined by high healthcare resource use. Compensating design features, such as the use of an appropriate comparison group of individuals satisfying the same criteria, can help address these concerns. For further discussion, see the Considerations section of this report.

The study design is observational rather than experimental, which is typical of population health management interventions where randomized studies are rarely feasible. As is typical for observational studies, the approach is subject to a range of potential biases and confounders that could threaten the validity of the findings; however, we found the approach used by OnTrak to be no more vulnerable to such biases or confounders than is typical for pre-post evaluations overall.

We also reviewed the eligibility criteria for enrollment in the OnTrak program and for inclusion in savings reconciliations. OnTrak excludes individuals with certain chronic and/or severe health conditions that may not benefit clinically from participation in the OnTrak program, or for whom a savings reconciliation would be more challenging, given the complex nature of their health conditions. We found these criteria to be reasonable for identifying a cohort of members likely to benefit from the program and for whom savings can reasonably be calculated, although we also found that more lenient criteria and more nuanced savings calculations could potentially allow for the inclusion of additional patients who may also benefit from the OnTrak program. Given the criteria that are currently in place, any savings reconciliations should be understood as a measure of OnTrak's performance for the populations that meet OnTrak's eligibility criteria. The generalizability of these outcomes to other populations is not known.

This report provides a description of OnTrak's approach for estimating cost savings from the program and discusses considerations and limitations of the methodology used.

## Methodology and data

OnTrak employs a pre-post approach comparing healthcare costs for individuals prior to and following their enrollment in order to measure healthcare cost savings to health plans from its OnTrak program. OnTrak identifies individuals for program participation and inclusion in savings reconciliations based on a number of clinical, cost, or demographic criteria. OnTrak's methodology follows three major steps: (1) the identification of individuals eligible for the program, (2) the enrollment and treatment of these eligible individuals, and (3) the measurement of outcomes based on a pre-post analysis. Below, we identify the eligibility criteria and savings reconciliation methodologies as we understand them based on the information provided for our review.

### PARTICIPANT ELIGIBILITY CRITERIA

OnTrak's participant eligibility criteria vary somewhat between health plan partners but generally include standards regarding health plan coverage, line of business, impactable costs, age, and clinical characteristics. These criteria intend to capture an eligible population that is both likely to benefit clinically from the OnTrak program and for whom savings can reasonably be calculated. For the most part, we view these criteria as business decisions that can be reasonably negotiated on a partner-by-partner basis without affecting the overall validity of a savings analysis. However, these criteria do impact the generalizability of any calculated results, and caution should be taken when estimating program results for population segments whose composition differs from those that met the agreed-upon eligibility criteria.

#### Health plan coverage

OnTrak may include any individual with active health plan coverage; although some health plan partnerships additionally exclude those with certain types of coverage (such as special needs plans) or those who are already enrolled in other population healthcare management interventions or programs. The specific lines of business that are included differ by health plan partner, and some partners target specific states or regions of the country, but overall OnTrak enrolls individuals in all three major payer segments (commercial, Medicare, and Medicaid).

#### Demographic and clinical criteria

Depending on the health plan partner, OnTrak enrolls individuals aged 18 to 84 with substance use disorders, anxiety, and/or depression. With some limited variance among health plan partners, individuals with any of the following conditions are excluded from OnTrak eligibility:

- End-stage renal disease (ESRD)
- HIV/AIDS
- Active cancer, cancer in the prior 12 months, or a history of high mortality rate cancers
- Hemophilia
- History of organ transplant
- Chronic paranoid schizophrenia
- Certain types of dementia
- Recent pregnancy
- Enrollment in hospice (end-of-life) care

We understand that in some cases health plan partners may ask OnTrak to enroll certain individuals who would not have otherwise met OnTrak's eligibility criteria. These individuals are enrolled (if interested in participating) but their financial outcomes are calculated and considered separately from other program participants.

#### Impactable costs threshold

OnTrak requires that individuals satisfy an "impactable cost" threshold over a baseline time period in order to be eligible for program participation. The specific cost threshold and time period is generally \$7,500 total over the preceding 12 months. Impactable cost thresholds do not vary for a health plan partner but do vary among health plan partners. In general, OnTrak defines impactable costs as facility and professional services excluding prescription drugs as well as claims that occur during a "shock month," defined as any calendar month where a member

experiences \$50,000 or more in costs for facility and professional care. Because the impactable costs threshold is consistent for all individuals within a health plan partner's population, the proportion of the population satisfying the criteria will differ by population segment and line of business. The use of a consistent impactable cost threshold for all participants from the same health plan partner has potential implications for the degree of regression to the mean that is occurring in the savings calculations (discussed further below).

### Other exclusions

OnTrak also excludes individuals for which a single surgery represented more than 50% of total baseline medical (facility and professional, but not pharmacy) costs, as well as individuals with more than \$100,000 in facility and professional healthcare costs in the baseline period. Individuals meeting these criteria may be likely to experience lower healthcare costs in later time periods regardless of their program participation status due to regression to the mean. These exclusions are intended to partially mitigate the potential impact of regression to the mean on savings calculations.

### SAVINGS RECONCILIATION

Within each health plan partner engagement, OnTrak periodically completes a savings reconciliation analysis (typically every six months) to determine the financial impact of the OnTrak program for participating individuals. This analysis is completed using a pre-post study design, where costs in the baseline period are compared (with some adjustments) to costs after enrollment in the OnTrak program to determine savings. Such reconciliations are completed separately by health plan partner, so financial results are not commingled among partners.

### Savings calculations

OnTrak calculates savings at the member level as follows:

$$Savings = \left[ \frac{Base\ period\ claim\ costs * Trend\ factor}{Base\ period\ member\ months} - \frac{Enrollment\ period\ costs}{Enrollment\ member\ months} \right] * Enrollment\ member\ months$$

Trend factors are intended to capture prevailing secular trends in the costs for healthcare services experienced by a health plan partner. The specific factors are generally established by comparing year-over-year changes in healthcare costs across the entire health plan population, exclusive of individuals eligible for OnTrak enrollment, but ultimately are subject to negotiation and mutual agreement between OnTrak and the health plan partner. Trend factors are developed and applied in aggregate across all types of care. Because savings calculations are sensitive to the chosen trend factors, we suggest that OnTrak and its health plan partners consider selecting appropriate external benchmarks for the trend factors, and that both parties should review these factors carefully and continue to reach mutual agreement on the particular factors to use for any given population.

OnTrak aggregates member-level savings at the health plan partner level, in some cases with segmentation between "regular" and "non-regular" members (further described below).

Note that the costs and member months in both the base and enrollment periods are exclusive of "shock months" (further described below).

### Regular and non-regular members

OnTrak makes certain clinical exclusions while determining program eligibility; however, some members newly develop or are first identified as having excluded conditions subsequent to their initial enrollment in the OnTrak program. OnTrak refers to individuals who are newly identified as having excludable clinical conditions after they have already enrolled as "non-regular" members and reports their savings results separately from "regular" members. Non-regular members may still have benefited from participation in the OnTrak program, but due to other complicating healthcare circumstances may have experienced cost patterns that make it challenging to identify the financial impact of the program. For this reason, OnTrak considers savings calculated for "regular" members to be more representative of overall program effect.

The regular member bucket contains members whose cost outcomes have not been impacted by the presence of predefined new comorbid conditions or cost exclusions. The precise list of new comorbid conditions and cost exclusions can vary by health plan partner, but generally are meant to exclude individuals or costs associated with medical conditions that are unlikely to be responsive to OnTrak's program. It generally includes all the clinical

exclusions listed in the Demographic and Clinical Criteria section above. It may also include other mutually agreed upon conditions. For example, members who are first diagnosed with asthma, diabetes, or chronic obstructive pulmonary disease (COPD) during the treatment period would be labeled as non-regular members.

Similarly, predefined costs may be excluded from both the pre- and post-periods, such as costs associated with pregnancy or hepatitis C medications. In these cases, the members subjected to such cost exclusions would also be labeled as non-regular.

### Shock costs

Any calendar month (in either the base or the enrollment time period) in which an individual experiences \$50,000 or more in healthcare costs is considered a “shock month.” Both the costs and member months for shock months are excluded from the savings reconciliation analysis.

The directionality or magnitude of any biases that may be introduced by the exclusion of shock months is not clear. In general, a fixed cost threshold may be more readily surpassed in later time periods than in earlier ones due to general healthcare cost inflation. However, individuals with complex healthcare needs that are better managed while enrolled in the OnTrak program may be less likely to experience the significant healthcare events that would result in a shock month during the enrollment period.

## Considerations

As noted previously, we found the approach outlined above to be a reasonable implementation of a pre-post study design. Pre-post study designs, while common in the evaluation of population health management programs, are subject to several limitations and potential biases, as are observational study designs more generally. Any results attributed to the OnTrak program should be understood within the context of these limitations. We describe what we view as the most impactful considerations below.

### REGRESSION TO THE MEAN

Regression to the mean is generally the most significant threat to validity in the study of care management programs, as these programs often identify and seek to enroll members (at least partially) on the basis of significant healthcare resource use. Healthcare resource use tends to regress toward the overall mean upon repeated observation for the same population, whether or not any particular intervention is applied. Adequately accounting for regression to the mean is one of the most important considerations when designing an evaluation study.

One of the criterion considered for identifying patients eligible for OnTrak is the level of “impactable costs” experienced by the patient in a baseline period. Because this threshold may have the effect of identifying individuals with high costs relative to demographically similar peers, regression to the mean could be a concern as the costs for such individuals are likely (on average) to regress toward the mean in later time periods, regardless of any programs or interventions that may have been applied. Because a fixed threshold is used across a health plan partner’s population, the impact of this threshold on regression to the mean likely differs by population segment (such as by age, sex, or line of business). We have not measured the impact of regression to the mean for any particular population and as a result cannot quantify the extent to which observed decreases in the total cost of care may be impacted by regression to the mean. Options for detecting and controlling for regression to the mean may be worth consideration.

### SELECTION BIAS AND CONFOUNDING

When participation in a population health management program is voluntary, it is generally the case that individuals who opt into the program differ systematically from individuals who do not. In some cases, these systematic differences are identifiable in the data available for study and can be controlled for, but in other cases the factors driving these differences are not observable with the available data. For example, if individuals who opt into the OnTrak program are experiencing meaningful changes in their life circumstances, these changes may be a meaningful source of confounding, as the changing circumstances (and the attending increased interest in engaging with care) could be the driver of both the decision to enroll in the program, and the ensuing reduction in healthcare costs. This possibility (and the possibility for other unobserved confounders) likely cannot be easily controlled for in this study design and is a potential limitation of the findings of the program evaluation.

## **ADJUSTMENT FOR TREND**

In the savings calculations, baseline costs are adjusted for trend and effectively serve as the “counterfactual” expected cost levels in the absence of any particular healthcare program or intervention. Adjusting for overall healthcare cost trend is a reasonable way to account for underlying secular trends in the price of healthcare services, but it does not fully account for how costs for the particular population enrolled in the OnTrak program might have reasonably been expected to develop in the absence of the OnTrak program. The set of individuals meeting OnTrak’s eligibility criteria are likely to experience different cost trends over time due to the complex (and in some cases progressive) nature of their health conditions. Their cost trends over time may also differ due to the natural regression of their costs to a population mean following any significant events that may have triggered their satisfaction of the impactable cost threshold. To the extent that “expected” healthcare cost trends for those who satisfied the eligibility criteria differ from those used to develop the trend factors, savings estimates may be biased.

## **ASSESSING STATISTICAL SIGNIFICANCE**

The savings calculations that we reviewed did not include any assessment for statistical significance. While we understand that OnTrak generally aims to generate healthcare cost savings results that would be in excess of the magnitudes necessary to produce a statistically significant result, we would suggest that incorporating some sort of assessment of statistical significance would be helpful, particularly for any health plan partners enrolling a relatively smaller panel of patients in the OnTrak program.

## **PLAUSIBILITY OF RESULTS**

Many factors impact healthcare costs, and cost reductions may not be fully attributable to savings introduced by the OnTrak program. For that reason, program cost savings should be evaluated alongside other metrics to help validate the plausibility of results. Examining healthcare costs over the duration of the study period may help substantiate results if healthcare cost impacts can be shown to coincide temporally with key program milestones. Examining results by service category (such as inpatient admissions, emergency room visits, professional services, etc.) can help lend further plausibility to the results if changes in costs over time correlate reasonably well to where the program was intended to have an impact (for example, a greater use of preventive services, greater medication adherence, additional psychiatric visits, fewer emergency room visits or hospitalizations, etc.). Additionally, cost impact estimates should be reasonably related to the initial estimation of impactable costs for the program. To the extent that these plausibility metrics do not align well with cost savings estimates, results may not be valid.

## **EXTERNAL VALIDITY OF RESULTS**

We found OnTrak’s eligibility criteria to be reasonable, and it is our opinion that the particular criteria used to identify individuals for participation in the program can be negotiated as a business decision without any substantive impacts on the validity of savings calculations. However, estimates of program effects for those who met OnTrak’s eligibility criteria may not be generalizable to other populations selected using other criteria.



## Data reliance and caveats

This report is intended to describe our opinion of the pre-post savings reconciliation methodology used by OnTrak to estimate the healthcare cost impact of its OnTrak program. Other uses may be inappropriate. This report is intended for the internal use of OnTrak and is only to be relied upon by OnTrak. This report may be shared with interested third parties if shared in its entirety. Milliman does not intend to benefit or create a legal duty to any third-party recipients of its work. The opinions presented herein are based on information provided by OnTrak via email on the following dates, as well as weekly phone conversations spanning the same time period:

- October 13, 2020
- October 20, 2020
- November 11, 2020
- November 19, 2020
- December 10, 2020
- January 7, 2021
- April 1, 2021

The conclusions described in this report apply only to the methodology that we reviewed, and not to any particular calculations, results, or conclusions. This work was completed under the consulting services agreement between OnTrak, Inc. (formerly known as Catasys, Inc.) and Milliman entered into on June 1, 2019.



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#### CONTACT

**Stoddard Davenport**  
[stoddard.davenport@milliman.com](mailto:stoddard.davenport@milliman.com)

**Doug Norris**  
[doug.norris@milliman.com](mailto:doug.norris@milliman.com)