Analysis of Type 2 Diabetes Reversal Cost Savings

Amy Zhang, FSA, MAAA, CERA
Wendy de Heer, PhD
Lisa Izquierdo
Dan Carpenter, MPH

virta

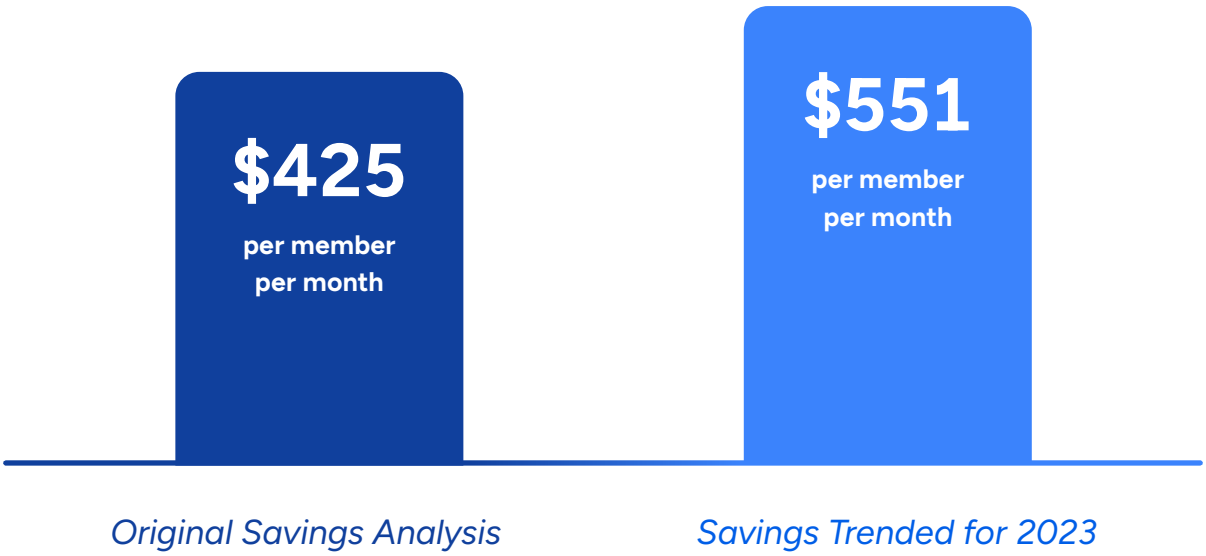
Important Update for 2023

This paper was originally published in 2021 and the included analysis is based on claims data from three of Virta's commercial deployments from 2017 to 2020.

Since 2020, we've witnessed increased inflation and a rise in drug costs. To account for this rise and provide a savings figure that is better aligned with the current economy, we trended the analysis for three years, using a 6.5% increase to medical costs and an 11.9% increase to Rx costs. These trend studies were used as a reference:

- The 2020 Global Medical Trend Rates Report by Aon reported a 6.5% regional average gross medical trend rate for the USA in 2020.
- The 2012–2017 ADA report, Economic Costs of Diabetes in the U.S showed an 11.9% annual increase to diabetes drugs between 2012–2017. Calculations are available upon request.

With this composite trend applied, in 2023 Virta's type 2 diabetes reversal program would deliver total gross savings of $13,212 over two years or $551 per member per month. Of these savings, $270 per month is pharmacy savings and $281 per month is medical cost savings.



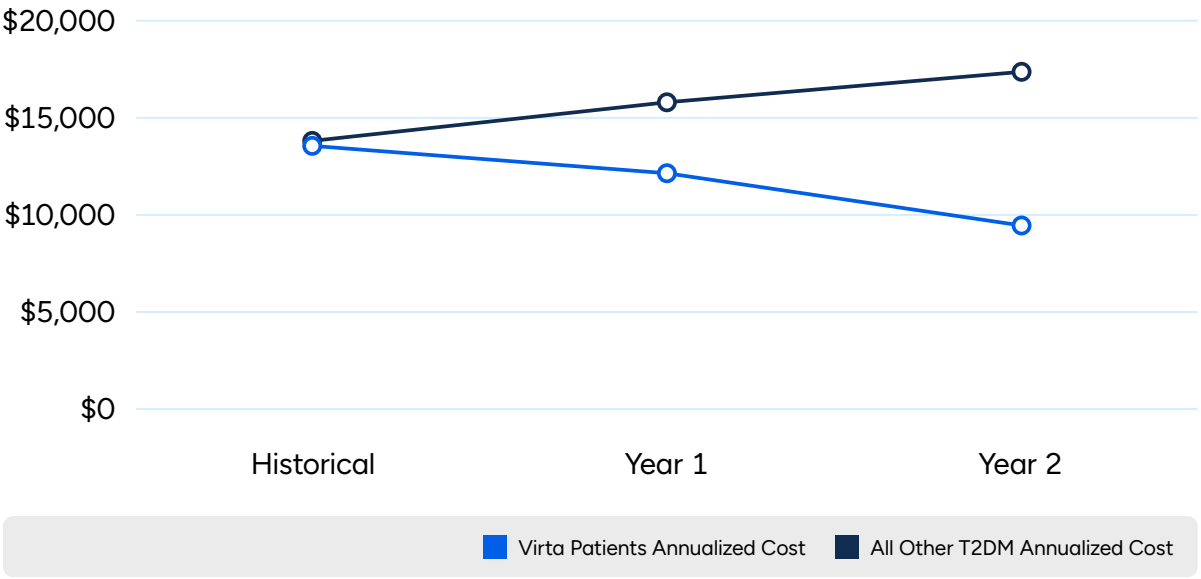
To preserve the integrity of the initial analysis, we have not made any changes to the following paper. However, we felt it was important to provide these trend updates to ensure the most up to date information was available.

Executive Summary

The purpose of this paper is to analyze cost savings of Virta's Type 2 Diabetes Mellitus (T2DM) Reversal program using claims data from three commercial deployments from 2017 to 2020. Virta's approach to diabetes is the first non-surgical treatment proven to reverse diabetes.[1] To safely reverse diabetes, Virta provides patients with individualized nutritional therapy, overseen by Virta physicians who titrate anti-diabetic medications as glucose levels drop, thereby mitigating diabetes drug dependence. In addition to a physician-led care team, Virta provides daily interactions with a dedicated health coach, diabetes testing supplies and related equipment, access to a patient community, and exclusive content such as meal plans. Through improved metabolic health, Virta patients are able to control glucose level. At one year, clinical trial patients still enrolled in the trial eliminated 63% of diabetes-specific medications. 94% of patients eliminated or reduced insulin usage.[2]

This study focuses on claim-based results for our early large commercial group deployments. Total savings over two years were $10,203 ($425 per member per month). During the first year, we observed total pharmacy and medical cost savings of $3,094 per member ($258 per member per month). During the second year, we observed total cost savings of $7,109 per year ($592 per member per month). All cost savings are on an allowed basis.

Figure 1: Annualized Allowed Costs Over Time



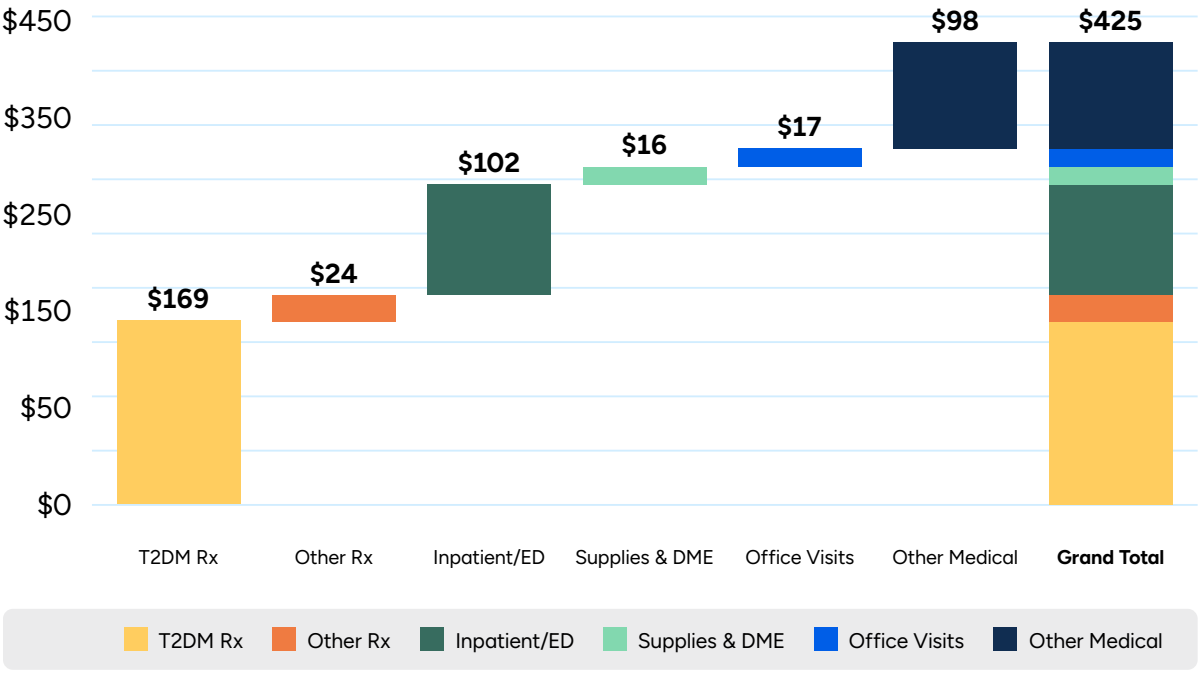
There is no standard methodology to perform this study, as operational constraints and commercial considerations make designing a randomized, controlled trial infeasible for a "real world" study. Our approach has been to compare Virta patients with at least six months of continuous treatment to all other members with T2DM from the same commercial groups. We applied exclusion criteria to both groups as described in the methodology section. We discuss the strengths and weaknesses of our methodology in the methodological considerations section.

(1) There were 435 Virta patients. The results of this study are based on 4,698 months of experience in Year 1, and 1,666 months of experience in Year 2. (2) All cost savings are on an allowed basis and do not include the impact of member cost sharing or rebates. Fees for diabetes reversal or diabetes management programs are not included above.

Results

To better understand pharmacy and medical cost savings achieved by Virta patients, we classified each pharmacy and medical claim into one of several categories. Figure 2 shows the breakout of total estimated savings over two years by service category on a per member per month (PMPM) basis.

Figure 2: Per Patient Savings (PMPM)



As can be seen in Figure 2 above, medications cost savings make up 45% of total cost savings over two years, including $169 PMPM from diabetes medications (T2D Rx) and $24 PMPM from other medications. The next largest category was from inpatient/ED claims making up 24% of savings, or $102 PMPM over two years. Supplies/DME and reduced office visits each contributed 4% of total savings, or $16 and $17 PMPM respectively. Finally, other medical savings, which may include other costs related to complications or replaceable services, made up 23% of savings, or $98 PMPM over two years.

Table 1 below provides allowed costs of the Virta patients as well as all other Type 2 Diabetes patients. More details can be found in Appendix A, Table 1b.

Diabetes medications were the strongest driver of cost savings, resulting in $159 PMPM of cost savings in Year 1 and $178 PMPM of cost savings in Year 2.

Other medications did not result in cost savings in Year 1. In Year 2, we observed a decrease in other medications for Virta patients. This was driven by a decrease in medications administered in a medical setting ("J Code" drugs). These drugs typically include cancer drugs and other drugs which cannot be self-administered. While our Year 2 results are based on limited experience, we highlight the reduction in J Code drugs which may be driven by random fluctuations or by the linkage between diabetes and cancer. We understand that future clinical research will investigate how Virta's Type 2 Diabetes Reversal program may impact the incidence and progression of cancers.

In our study, we investigated savings from complications of diabetes through examination of inpatient claims, Emergency Department visits (ED), cardiology claims, and supplies/DME services. We discuss this approach further in the methodology and methodological considerations section. While we observed an increase in inpatient costs during Year 1 for Virta patients, the increase in inpatient costs was greater for non-Virta patients; therefore, we calculated cost savings for inpatient admissions to be $26.60 PMPM. In Year 2, inpatient costs for Virta patients decreased compared to baseline, while inpatient costs for non-Virta patients continued to increase, resulting in $180.92 of cost savings. Supplies and DME showed a sustained decrease for Virta patients and appeared to result in cost savings in Year 1 and Year 2. As noted above, Virta does provide some diabetic supplies; however the DME noted here is not generally provided through Virta. In Year 1 and Year 2, both cardiology and ED did not appear to result in cost savings.

Table 1: Per Member Per Month Comparison of Virta Patients to All Other Patients

	Virta Patients (PMPM)			Other T2 Diabetes Patients (PMPM)			Cost Savings PMPM	
	Historical	Year 1	Year 2	Historical	Year 1	Year 2	Year 1	Year 2
T2DM Rx	$308.81	$175.50	$176.04	$212.51	$238.65	$257.96	$159.45	$178.21
Other Rx	$200.03	$227.63	$141.88	$218.86	$236.71	$217.86	-$9.74	$57.15
Subtotal: Rx Claims	**$508.83**	**$403.13**	**$317.92**	**$431.37**	**$475.37**	**$475.82**	**$149.71**	**$235.37**
Complications	$201.32	$241.26	$145.54	$332.00	$412.96	$455.81	$41.01	$179.60
Replaceable Services	$92.96	$82.47	$66.12	$91.57	$89.01	$89.42	$7.93	$24.69
Other Medical	$326.84	$287.02	$284.75	$303.43	$322.82	$414.08	$59.21	$152.74
Subtotal: Medical Claims	**$621.13**	**$610.76**	**$496.400**	**$727.00**	**$824.79**	**$959.31**	**$108.15**	**$357.03**
Grand Total	**$1,129.96**	**$1,013.88**	**$814.32**	**$1,158.37**	**$1,300.15**	**$1,435.13**	**$257.85**	**$592.40**
Annualized Cost	**$13,559**	**$12,167**	**$9,772**	**$13,900**	**$15,602**	**$17,222**	**$3,094**	**$7,109**

Replaceable services include labs and office visits. The Virta treatment includes services and supplies that should replace services typically covered through medical insurance, such as diabetes supplies (including test strips & lancets), physician office visits, and outpatient labs. For our study, diabetic test strips & lancets were covered through the pharmacy benefit and were included under "Diabetes Medications" since these were handled by the pharmacy benefit manager and dispensed at retail pharmacies. In Year 1 and Year 2 we observed a reduction in office visits which generated cost savings.

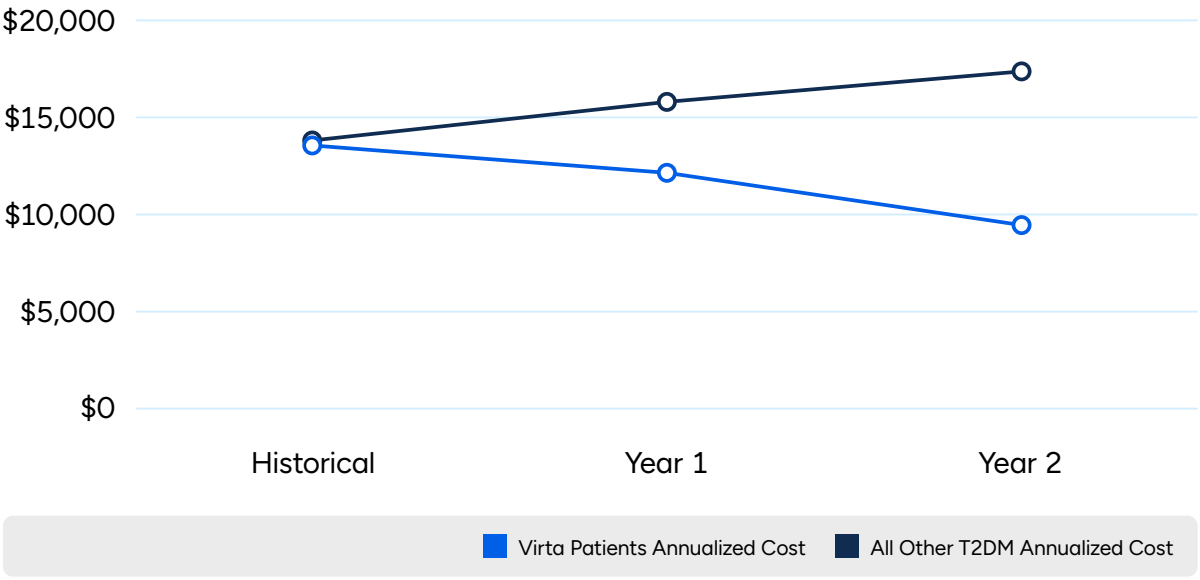
Finally, all other claims were classified as "Other Medical". Due to limitations in our methodology, it is likely that "Other Medical" contains medical services for complications and replaceable services. For instance, it may contain complications from cancer treatments, podiatry (complications), and other ancillary services performed during office visits (replaceable). Also, "Other Medical" may contain claims related to behavioral health. We observed cost savings generated by decreased

(1) There were 435 Virta patients. The results of this study are based on 4,698 months of experience in Year 1, and 1,666 months of experience in Year 2. (2) All cost savings are on an allowed basis and do not include the impact of member cost sharing or rebates. (3) Cost savings are calculated using the difference-in-differences, for instance ([Historical Virta] - [Year 1 Virta]) - ([Historical Other] - [Year 1 Other]). Using Diabetes medications as an example, cost savings would be ($308.81 - $175.50) - ($212.51 - $238.65) or $159.45. (4) Fees for diabetes reversal or diabetes management programs are not included above.

"Other Medical" costs for Virta patients and a corresponding increased "Other Medical" costs for non-Virta patients.

In Figure 3 below we show the per member per month allowed costs over time for Virta patients and all other T2DM patients.

Figure 3: Per Member Per Month Costs Over Time



In Table 2, we show the change from baseline for costs for each of the categories in Table 1. In total, we observed that for all other type 2 diabetes patients, costs increased by 12.2% in Year 1 and 23.9% in Year 2 as compared to baseline. At the same time, total costs decreased by 10.3% in Year 1 for Virta patients and 27.9% compared to baseline. A negative value indicates reduction in costs; a positive value indicates an increase in costs.

From the perspective of cost savings as a % change from baseline, we also see that in Year 1 diabetes medications (-43.2% cost savings as compared to baseline) and supplies and DME (-79.8% savings as compared to baseline) were the two most favorable performing categories of claims. These two areas also performed well in Year 2 with a 43.0% decrease in the cost of diabetic medications in Year 2 and a 82.2% decrease in the cost DME and supplies. Other areas of strong performance include office visits and labs. The consistent reductions observed for these services indicate sustained results achieved by Virta patients over two years.

(1) There were 435 Virta patients. The results of this study are based on 4,698 months of experience in Year 1, and 1,666 months of experience in Year 2. (2) All cost savings are on an allowed basis and do not include the impact of member cost sharing or rebates. Fees for diabetes reversal or diabetes management programs are not included above.

Reasonableness Assessments

To assess the reasonableness of our results, we reviewed other studies relating to Virta's Type 2 Diabetes Reversal program as well as other studies on the cost of Type 2 Diabetes.

We compared the reduction in costs for diabetes medications for Virta patients with results from the clinical trial.[2] We found that the cost reduction observed in our study here (43.2% reduction in costs for Virta patients compared to the baseline) is consistent with these previously published clinical results.

- The clinical results showed that at baseline 55.5% of Virta patients took a diabetes medication other than metformin, while at 1 year, 28.0% of patients took any diabetes medication other than metformin. This would be a reduction of 49.5% for users of any diabetic medication.
- The clinical results showed that at baseline 28.4% of Virta patients took insulin where at 1 year, 15.1% of patients took insulin. This would be a reduction of 46.8% for insulin users.

Table 2: Percentage Cost Change as Compared to Baseline

	Virta Patients (PMPM)		Other T2 Diabetes Patients (PMPM)	
	Year 1	Year 2	Year 1	Year 2
T2DM Rx	-43.2%	-43.0%	12.3%	21.4%
Other Rx	13.8%	-29.1%	8.2%	-0.5%
Subtotal: Rx Claims	**-20.8%**	**-37.5%**	**10.2%**	**10.3%**
Complications	19.8%	-27.7%	24.4%	37.3%
Replaceable Services	-11.3%	-28.9%	-2.8%	-2.3%
Other Medical	-12.2%	-12.9%	6.4%	36.5%
Subtotal: Rx Claims	**-20.8%**	**-37.5%**	**10.2%**	**10.3%**
Grand Total	**-10.3%**	**-27.9%**	**12.2%**	**23.9%**

It is challenging to monetize and compare the clinical results to our study, however the magnitude of savings in our study aligns with the projected savings based on our clinical results. Also, we consider the possibility that real-world cost reductions would be of a smaller magnitude than demedication from clinical trial results. For instance, we anticipate that de-medicated patients may have remaining unused medication, waste that would reduce cost savings in our study, but would not be captured in a clinical study. Counteracting this effect, it is also common for some patients to experience dosage reductions which translate to cost savings.

(1) There were 435 Virta patients. The results of this study are based on 4,698 months of experience in Year 1, and 1,666 months of experience in Year 2 for Virta Patients. (2) All cost savings are on an allowed basis and do not include the impact of member cost sharing or rebates. (3) All values are a % as compared to the baseline. Virta patients are compared to Virta baseline; Other T2DM patients are compared to the Other T2DM baseline. (4) Fees for diabetes reversal or diabetes management programs are not included above.

We also compared our results to the attributable cost of diabetes as published by the American Diabetes Association.[3] We were able to use this study to assess the reasonableness of the cost trends for non-Virta patients. Also, we assessed the reasonableness of our cost savings results with the attributable cost of diabetes. We found that our results appeared reasonable and consistent with this study.

A 2021 study of 590 VA patients with diabetes showed significant reductions in outpatient visits and diabetes medication fills. The study relied on a difference-in-differences analysis with a waitlist-control group—a quasi-experimental methodology and was based on VA electronic health records from 2018–2020 (rather than claims data used in this study). The study did not find any significant change in emergency department visits.[4] We compared our results to this study, and also noted a strong reduction in office visits as well as medication costs. Our results also did not demonstrate a reduction in ED visits when using the difference-in-differences technique.

We note that the estimated cost savings during Year 2 from inpatient medical claims was a robust driver of overall cost savings and assessed our results for reasonableness. In particular, inpatient costs may show high variance when small sample sizes are used. As described above, first we compared our results to the attributable cost of diabetes related to inpatient admissions. We also compared our results to literature which suggests that a 1.0 reduction in A1C can result in roughly 10% reduction in medical costs due to complications.[5] Medical costs in Year 1 and 2 averages to $892 PMPM among T2DM non-Virta patients. Comparing the inpatient and ED cost of Virta patients to T2DM non-Virta patients, we observe a $102 PMPM savings, or 11.4% of medical costs. Finally, we note that our study includes COVID-19 experience, and emerging data suggests greater weight loss elicited by the Virta treatment is associated with lower likelihood of hospitalization due to COVID-19 among Virta patients with type 2 diabetes.[6] COVID-19 could also explain some of the results.

Methodology

Savings are developed from comparing T2DM Virta members to T2DM non-Virta members. We included only members with a diagnosis code for T2DM (ICD-10 beginning with E11) on a medical claim.

For non-Virta patients, we picked an artificial "intervention date" to match the typical date of registration for Virta patients within the same commercial group. This allows us to develop a historical baseline, and Year 1 and Year 2 for each patient. For Virta patients, the actual date of registration with Virta is used, which varies by patient.

Next, we applied the exclusion criteria to ensure that each member had an adequate baseline, to ensure that each member had an adequate amount of experience, to exclude specified medical conditions, and to exclude patients who do not appear to utilize insurance. Applying clinical exclusions also has the effect of eliminating many high-cost claimants. This may have the tendency to prevent results biased by outliers or otherwise driven by reversion to the mean. Further detail on exclusions may be found in Appendix B.

Once exclusions have been performed, the two populations appear reasonably comparable based on our review of costs (see Table 1). The study contains 435 Virta patients from these 3 deployments, and the reference population contains 5,354 T2DM non-Virta patients.

In order to assess how comparable the populations were, we examined how likely a typical eligible individual was to become a Virta patient using characteristics such as age, gender, historical inpatient costs, historical office visit costs, and historical ED costs. The difference was not significant between Virta patients and non-Virta patients, indicating that the two populations

were suitable for comparison. However, we did determine that the two populations had a difference in diabetes medications costs that was statistically significant, whereby the population who enrolled in Virta had higher historical diabetes medication costs than the reference population. Thus, we determined that not adjusting for the difference is a conservative approach and would likely result in underestimation of Virta's true savings. This is because the dollar increase on drug costs will be more significant for a population with higher baseline drug costs. If we were to adjust for higher baseline drug costs on the reference population, we expect to observe more drug cost increases that would manifest as higher savings when compared against the Virta patient group. Additional discussion of the "match" of the two populations can be found in the methodological considerations section.

In our study, the average age of Virta patients is 53.8 and non-Virta patients is 54.4.

PMPM allowed costs of Virta treatment group are examined and compared to the reference population by period, which is split into: 1) Historical period (6 months prior to Virta deployment date); 2) Period 1, or Months 1–12 of intervention; and 3) Period 2, or Months 13–24 of intervention. Then savings are calculated using difference in differences: Virta and non-Virta member costs are compared by period to calculate the "difference" for historical period, period 1, and period 2; then difference in differences is calculated as the PMPM cost difference between period 1 (or period 2) and the historical period. Historical period data is limited to 6 months due to data availability and accessibility, longer historical period experience is desired. Preliminary results of the two-year gross cost savings under baseline methodology is summarized in Table 1 and Table 1b.

We use service incurred dates to more accurately attribute claims to their respective periods. To minimize Incurred But Not Paid (IBNP) claims in our study periods, we have allowed for 3-months of run-out period on incurred claims at which point the data appear to be over 95% complete.

Allowed claims are used in the study as opposed to paid claims due to several considerations. Our participants in the study are enrolled in various health plans with diverse plan designs, and many had opportunities to change health plans during our study period. Paid claims are sensitive to plan designs and may skew our results. Furthermore, paid claims understate true care costs as they only capture the health plans' share.

Methodological Considerations

There is no standard methodology to perform this type of study. We have taken a straightforward approach by presenting data for all Virta patients compared to all other T2DM patients. We feel that this approach is reasonable for Virta's intervention for several reasons. Foremost, there is already well controlled clinical literature on Virta's intervention.

Also, Virta's intervention is widely available to Type 2 diabetes patients—it's available to everyone aged 18–79 with a limited list of clinical exclusion criteria for safety measures. Our commercial groups who are plan sponsors work to market and promote the availability of the Virta treatment. Therefore, we see very similar age and gender between Virta patients and other diabetes patients receiving usual care.

Note that Virta markets to all Type 2 Diabetes patients in a deployment and does not cherry-pick its participants based on potential to reduce costs to the plan. Acceptance into the Virta program is only contingent on patients' health to safely participate in the program. Quite often, other disease management programs enroll patients who have a recent history of hospitalizations or other high cost events, which biases the intervention population. In those cases, this methodology would not have been appropriate.

Finally, we recognize that our audience for this paper may include those without advanced statistical or actuarial training. Our straightforward approach provides results without complications which may be introduced from statistical methods.

COVID-19 Impact

COVID-19 had an observable impact on utilization in 2020. Our approach to COVID-19 has been to ensure that both the Virta patients and the reference population included date ranges with similar 2020 COVID-19 experience. We have implicitly assumed that this approach appropriately handles COVID-19; however, it is possible that COVID-19 has biased the study in ways that would be difficult to identify and address. The following aspects may have been changed by COVID-19:

- Members' propensity to enroll in Virta treatment
- Members' adherence to Virta treatment
- Medical/Rx plan utilization rate during COVID-19

Selection Bias

Selection bias can take many forms. It is generally the risk that it would not be possible to compare Virta patients to all other T2DM patients due to some underlying issue with how patients engage and register with Virta. This could occur, if registration caused Virta patients to have a different demographics than other T2DM. When we reviewed the age and gender of patients between the Virta patients and other T2DM patients for each group, we did not see a difference.

This could also occur if perhaps Virta patients were more motivated to "get healthy". One indication that selection bias is not an issue is the independent recruitment of patients during the clinical studies, which showed clear demedication results with the Virta intervention as compared to usual care. In this study, the Virta patients and usual care patients were independently recruited.[2]

When comparing the Virta member population to the reference population under baseline methodology, we see that Virta members have higher diabetes medication costs during the historical period than the reference population. This difference could imply: 1) higher acuity with Virta enrollees which drives higher medication costs; and/or 2) higher Rx adherence prior to Virta intervention. The former would imply that less healthy patients engaged with Virta and raise the possibility that Virta's intervention has excelled at reducing costs for a less healthy population. The latter might imply that Virta patients are "more motivated"; however, there would also be less opportunity for savings from complications. Thus, there exists potential for selection bias to impact our study in both directions and we do not believe observed savings are attributable to selection bias.

For future claims-based studies of Virta's intervention, we may consider additional matching criteria, for instance matching on the length of an intensive diabetes management intervention, date of initial T2DM diagnosis, drug regimen, and complications/comorbidities.

Persistency Bias

We define persistency bias as the tendency for a population to become healthier over time as the less healthy members drop out from the group. For a retrospective cohort study on a disease management program, this issue may generate the appearance of savings which is actually attributable to the change in population rather than change in health of the population.

For Virta, disenrolling members appear to be of younger age, leaving the population that "persists" in the program to be older and potentially of higher costs. Hence, we do not believe observed savings is attributable to persistency bias.

Comparable Duration

We have examined the Virta population and the reference population for the average duration per member in our data to ensure our analysis is not skewed by temporal difference in underlying trends. We have found the difference in member months per member in each period between the two populations to be within 0.1 months on a rounded basis.

Disclosures and Limitations

The purpose of this study is to assess whether the Virta's Type 2 Diabetes Mellitus Reversal treatment produces savings for a commercial payer. Data and information published in this report may not be suitable and should not be used for other purposes. This report should only be reviewed in its entirety.

The estimations described in this report are not predictions. Rather, they are estimations of consequences that will occur if the underlying assumptions are realized precisely. Actual experience will deviate from these projections due to a variety of influences.

Random fluctuations in the incidence and severity of claims will impact the extent to which results for claims-based analysis may provide consistent insights. In particular, groups of less than 500 members present a higher risk for random fluctuations in results.

The results of this analysis are based on a specific set of assumptions.

Where noted, we relied on assumptions from experts. All assumptions were reviewed for reasonableness and compared to previous work with similar projects.

We relied on data sources from Virta, employer groups, and third parties such as the American Diabetes Association. We reviewed the data for reasonableness including the relationship between data sources, but did not audit the data.

Amy (Mengyun) Zhang is a member of the American Academy of Actuaries and meets the qualification standards to perform this analysis.

Appendix A. Detailed Results Tables

Table 1b. Per Member Per Month Comparison of Virta Patients to All Other Patients

	Virta Patients (PMPM)			Other T2 Diabetes Patients (PMPM)			Cost Savings PMPM	
	Historical	Year 1	Year 2	Historical	Year 1	Year 2	Year 1	Year 2
Diabetes Medications	$308.81	$175.50	$176.04	$212.51	$238.65	$257.96	$159.45	$178.21
Other Medications	$200.03	$227.63	$141.88	$218.86	$236.71	$217.86	-$9.74	$57.15
Subtotal: Rx Claims	**$508.83**	**$403.13**	**$317.92**	**$431.37**	**$475.37**	**$475.82**	**$149.71**	**$235.37**
Inpatient	$156.09	$213.02	$109.04	$290.58	$374.11	$424.46	$26.60	$180.92
ED	$13.64	$13.65	$9.88	$18.13	$15.91	$13.13	-$2.33	-$1.25
Supplies and DME	$19.79	$4.00	$3.52	$9.19	$10.16	$7.62	$16.77	$14.70
Subtotal: Complications	**$189.53**	**$230.66**	**$122.45**	**$317.91**	**$400.18**	**$445.20**	**$41.14**	**$194.37**
Office Visits	$61.81	$52.42	$43.86	$54.44	$54.97	$60.16	$9.91	$23.67
Labs	$31.15	$30.05	$22.26	$37.12	$34.04	$29.26	-$1.98	$1.02
Subtotal: Replaceable	**$92.96**	**$82.47**	**$66.12**	**$91.57**	**$89.01**	**$89.42**	**$7.93**	**$24.69**
Other Medical	**$338.64**	**$297.62**	**$307.83**	**$317.53**	**$335.60**	**$424.69**	**$59.08**	**$137.97**
Grand Total	**$1,129.96**	**$1,013.88**	**$814.32**	**$1,158.37**	**$1,300.15**	**$1,435.13**	**$257.85**	**$592.40**
Annualized Cost	**$13,559**	**$12,167**	**$9,772**	**$13,900**	**$15,602**	**$17,222**	**$3,094**	**$7,109**

Table 2b. Percentage Cost Change as Compared to Baseline

	Virta Patients (PMPM)		Other T2 Diabetes Patients (PMPM)	
	Year 1	Year 2	Year 1	Year 2
Diabetes Medications	-43.2%	-43.0%	12.3%	21.4%
Other Medications	13.8%	-29.1%	8.2%	-0.5%
Subtotal: Rx Claims	**-20.8%**	**-37.5%**	**10.2%**	**10.3%**
Inpatient	36.5%	-30.1%	28.7%	46.1%
ED	0.0%	-27.5%	-12.3%	-27.6%
Supplies and DME	-79.8%	-82.2%	10.6%	-17.1%
Subtotal: Complications	**21.7%**	**-35.4%**	**25.9%**	**40.0%**
Office Visits	-15.2%	-29.0%	1.0%	10.5%
Labs	-3.5%	-28.5%	-8.3%	-21.2%
Subtotal: Replaceable	**-11.3%**	**-28.9%**	**-2.8%**	**-2.3%**
Other Medical	**-12.1%**	**-9.1%**	**5.7%**	**33.7%**
Grand Total	**-10.3%**	**-27.9%**	**12.2%**	**23.9%**

Appendix B. Exclusion Criteria

Members meeting any of the following criteria are excluded from the study.

Less than $250 ALLOWED

Member had less than $250 total allowed.

Reason for exclusion: It is not likely for a member with diabetes to have <$250 total allowed, therefore it is likely that we do not have member's comprehensive claims data (e.g. member has another insurance), or records associated with the member suffer from data quality issues.

Excluded Diagnosis

Member who had a diagnosis code that is not appropriate for the Virta treatment.
This includes: heart failure, pregnancy, schizophrenia/bipolar, and ESRD.

- Relevant ICD-10 Codes:
- Heart Failure: I50.XX
- Pregnancy: OXX.XX
- Schizophrenia/bipolar: F20.XX, F31.XX
- ESRD: N185.XX, N186.XX

Reason for exclusion: These exclusion criteria were based on internal clinical guidelines during the study period, 2017-2020 which recommended that the Virta treatment was not suitable for individuals with some medical conditions. These exclusions are typically available in the standard "Statement of Work" signed between Virta and customers. We find that patients with these exclusion criteria have much higher costs and present challenges to develop a suitable "match" between the two groups. Please note that Virta physicians do allow some low acuity CHF patients to begin the Virta treatment. Introducing these patients to the study adds difficulty in finding a suitable comparison population or adds selection bias to our analyses.

Inadequate experience eligibility

Member who had less than 9 consecutive months of experience, or had less than 4 months of historical experience prior to the intervention.

Reason for exclusion: We wouldn't have sufficient data to draw reliable conclusions based on these members with a short claims experience period.

Inadequate experience intervention

Member who had less than 6 months of experience after the intervention date.

Reason for exclusion: We wouldn't have sufficient data to draw reliable conclusions based on these members with a short claims experience period.

Prediabetes

Member who was not enrolled in the Type 2 Diabetes Reversal Program, but was enrolled in the Prediabetes program.

Reason for exclusion: The study focuses on results of the Type 2 Diabetes Reversal Program, and members from other programs shall be excluded.

Appendix C: Claim Classification

We relied on the following logic to classify claims. The logic is applied in order below and applied to each claim line. For example, if a claim line is classified as "Inpatient", it cannot later be classified as "Labs".

Diabetes Medications. Diabetes medications also include diabetic supplies and equipment provided at a retail pharmacy or paid through the pharmacy benefit manager (PBM). We identified diabetes medications using a list of national drug codes (NDCs) which includes:

- **Drugs:** Insulins, GLP-1s, SGLT-2s, DPP-4s, Metformins, Meglitinides, Sulfonylurea, Thiazolidinedione, and diabetic combinations thereof or
- **Supplies and Equipment:** Lancets, devices, test strips, readers, and needles

Other Medications. Other Medications includes:

- Any other claim at a retail pharmacy or paid through the PBM with an national drug code (NDC) or
- **CPT/HCPCS:** JXXXX which is all office administered drugs, that is medical claims with a HCPCs beginning with a "J".

Inpatient. For claims data received during this study, the inpatient classification logic relies primarily on place of service. We reviewed these claims and it appears that this logic was accurately capturing all inpatient facility & professional costs.

- **Place of Service:** Inpatient Hospital or
- **Place of Service Code:** 21

ED. The ED logic relies on CPT codes & place of service. The logic does not identify observation stays and may not identify imaging or surgery services performed related to an ED visit.

- **Place of Service:** Emergency Room or
- **Place of Service Code:** 23 or
- **CPT/HCPCS:** "99281", "99282", "99283", "99284", or "99285"

Office Visits. The office visit logic relies on E&M CPT codes and does not identify other services performed during the office like blood tests.

- **CPT/HCPCS:** "99201", "99202", "99203", "99204", "99205", "99211", "99212", "99213", "99214", "99215", "G0438", or "G0439"

Labs. The lab's logic includes all labs and venipuncture, which may include services not directly related to T2DM, for instance pathology. It relies on CPT codes & place of service.

- **CPT/HCPCS:** "8XXXX" or
- **CPT/HCPCS:** "36415" or "36416' or
- **Place of Service:** Independent Laboratory or
- **Place of Service Code:** 81

Supplies and DME. Supplies and DME include a range of supplies, devices, and durable medical equipment (DME) which are paid through medical claims. This category may be composed of services related to complications (for instance, footwear) as well as replaceable services (for instance, insulin pumps). It appeared that the majority of the costs in this category were for complications of diabetes. This logic relies on CPT codes.

- **CPT/HCPCS:** "EXXXX" (Durable medical equipment) or
- **CPT/HCPCS:** "KXXXX" (Durable medical equipment prosthetics, orthotics, supplies and dressings) or
- **CPT/HCPCS:** "LXXXX" (Orthotic and prosthetic procedures, devices)

Other Medications. Other Medications also included the following medical claims.

- **CPT/HCPCS:** JXXXX which is all office administered drugs, that is medical claims with a HCPCs beginning with a "J".

Other Medical. All remaining medical claims are identified as other medical. This category may contain services which are replaceable or related to complications.

Citations and Notes

1. Virta's definition of diabetes reversal: HbA1c below 6.5%, with the elimination of all diabetic medications except for metformin. Metformin is excluded from these reversal criteria because it is not diabetes-specific.

2. Hallberg SJ, McKenzie AL, Williams PT, et al. Effectiveness and Safety of a Novel Care Model for the Management of Type 2 Diabetes at 1 Year: An Open-Label, Non-Randomized, Controlled Study [published correction appears in Diabetes Ther. 2018 Mar 5;:]. Diabetes Ther. 2018;9(2):583-612. doi:10.1007/s13300-018-0373-9

3. American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. Diabetes Care. 2018;41(5):917-928. doi:10.2337/dci18-0007

4. Strombotne KL, Lum J, Ndugga NJ, et al. Effectiveness of a ketogenic diet and virtual coaching intervention for patients with diabetes: A difference-in-differences analysis [published online ahead of print, 2021 Aug 5]. Diabetes Obes Metab. 2021. doi:10.1111/dom.14515

5. Fitch KV, Iwasaki K, Pyenson BS. The cost and quality gap in diabetes care: an actuarial analysis. Milliman Client Report. Published on Jan 30, 2012. Accessed August 20, 2021. https://www.milliman.com/en/insight/the-cost-and-quality-gap-in-diabetes-care-an-actuarial-analysis.

6. Diabetes Reversal Leader Virta Health Demonstrates Promising Results on Mitigating COVID-19 Severity for People with Type 2 Diabetes. Virtahealth.com. https://www.virtahealth.com/blog/diabetes-reversal-leader-virta-health-demonstrates-promising-results-on-mitigating-covid-19-severity-for-people-with-type-2-diabetes. Published on June 28, 2021. Accessed on August 20, 2021.