Economic Impact on the Healthcare System using an FDA-Cleared Mild Brain Injury/Concussion Assessment Device

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Abstract

Over 30% Cost Savings to Payers and Patients Calculated from the BrainScope One Economic Analyzer Model (BEAM)

Escalating awareness of the short and long-term consequences of traumatic head injury, even when mild, has resulted in an increasing burden to the health care system to the extent of $76.5 billion annually.[1,2] This white paper demonstrates potential cost reductions as high as 32.2%, shared between payers and patients when the *BrainScope® One* medical device is integrated into the patient care pathway.

Adoption of *BrainScope One* expands care access points for head injury to Urgent Care Centers (UCC) and Physician offices, more cost efficient and accessible environments. It can also improve patient triage in the Emergency Department (ED) by diverting patients from unnecessary CT scans. *BrainScope One* has been demonstrated to aid in more objective, accurate, rapid, and safer diagnosis of mild Traumatic Brain injury (mTBI/concussion), resulting in significant benefits across the healthcare system. This paper assesses *BrainScope One*'s impact on the health care system and specifically examines the potential cost savings to patients and payers using the BrainScope Economic Analyzer Model (BEAM). Utilizing realistic inputs, this model illustrates the significant opportunity for cost savings (as high as 32%) through adoption of *BrainScope One*.

1. Introduction

An estimated 4.8 million people are evaluated annually in the US for traumatic brain injuries (TBI), approximately 94% of whom are found to be "mild" by current clinical criteria.[3] These numbers do not reflect the large number of those injured in recreational, sports and other activities who do not seek treatment and go unreported. Heightened awareness of the potential for short-term and long-term consequences of head injury has resulted in a 29.1% increase in Emergency Department (ED) visits for head injury between 2006 and 2010, while overall ED visits have only increased 3.6%.[3,4] Currently, more than 80% of head injured patients who go to the ED receive a CT scan, of which 91% are found to be negative.[3] The number of negative CT scans, the cost of ED treatment, and the risk of radiation exposure highlight the need for more effective screening tools in the mTBI (mild traumatic brain injury) diagnostic care path.[5,6,7]

BrainScope One is a first of its kind FDA cleared medical device, utilizing electrophysiological (EEG) biomarkers to aid in the objective assessment of the full spectrum of mTBI, including concussion, at the point of care. This handheld, easy to use medical device rapidly assesses the likelihood of both structural (brain injury visible on CT) and functional brain injury (such as concussive injury). The device is currently applicable for assessment of mildly presenting head injured

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Figure 1: Image showing *BrainScope One* assessment, with headset placed on patient's forehead and the handheld device being used by the clinician

patients (Glasgow Coma Scale (GCS)=13-15, including mTBI/concussion) between the ages of 18-85 years, within 72 hours of injury. *BrainScope One* is suitable for use in a variety of clinical settings including emergency departments, urgent care centers, and physicians' offices.

BrainScope One outputs the results of two EEG based biomarkers, one that informs the user of the likelihood of a structural brain injury (e.g., bleed) visible on CT or other advanced neuroimaging, and the Brain Function Index (BFI) that indicates the probability of brain function impairment. The structural injury algorithm has been demonstrated to have 99% sensitivity to the presence of ≥1 cc of blood, with specificity well above that of conventional clinical CT decision rules, and Negative Predictive Value[iv] (NPV) of 98%.[8] A retrospective study of data from the *BrainScope One* FDA prospective validation trial compared CT referrals for mildly presenting head injured patients based on standard clinical practice in the ED with those that incorporated *BrainScope One*, and demonstrated a potential 26% decrease of CT referrals.[9] A white paper from the BrainScope national Registry replicated these results in clinical practice, demonstrating 32.8% reduction of CT referrals in the ED.[10] In the Urgent Care Center (UCC) setting, data from the BrainScope national Registry demonstrated a potential reduction in ED referrals of up to 75% in mTBI concussed patients when *BrainScope One* was integrated into the initial evaluation.[11] These studies exemplify the potential benefits to the healthcare system when initial head trauma assessment is aided by objective results from *BrainScope One*.

There are substantial savings to be accrued with a timely, cost-effective diagnosis during the initial visit for head trauma. This white paper will explore the potential savings associated with the integration of *BrainScope One* in the care pathway of such patients. The *BrainScope One* Economic Analyzer Model (BEAM), is an actuarially developed model constructed to assess the economic impact of *BrainScope One* on mTBI costs to payers as well as patients. Furthermore, the model also demonstrates some of the broader impact of the device on the healthcare system.

[iv] *Negative predictive value* is the probability that subjects with a negative screening test truly do not have the disease.

2. Methods

2.1 *BrainScope One* Economic Analyzer Model (BEAM)

The *BrainScope One* Economic Analyzer Model (BEAM) is designed to illustrate the potential impact on payers (insurers; employers; government) and patients due to the integration of the device into the clinical care pathways for the assessment of mildly presenting traumatic head injuries. The model shows the net economic impact, as well as a more detailed cost-savings breakdown for payers and patients, which represent a portion of overall benefits to the healthcare system. It does this by comparing the current pathway to the new pathway that can be achieved by *BrainScope One* implementation. The model specifically examines the impact within the ED (patients arriving either via ambulance (EMS) or Walk-ins), UCCs, and Physicians' Offices, as these are the primary patient care settings in which integration of the *BrainScope One* device would be most applicable. This white paper categorizes these settings into "Emergency Department" (Walk-ins and EMS) and UCC and Physicians' Offices ("Community") for ease of comparison. Figure 2 provides a simplified visual representation of how *BrainScope One* can be integrated into the care pathway in each setting. In the ED (left panel), *BrainScope One* can be used at the point of triage to aid in assessing the need for a CT scan. In the Community setting (right panel), *BrainScope One* integration can add objective information to aid in determining the need for referral to the ED for a CT scan.

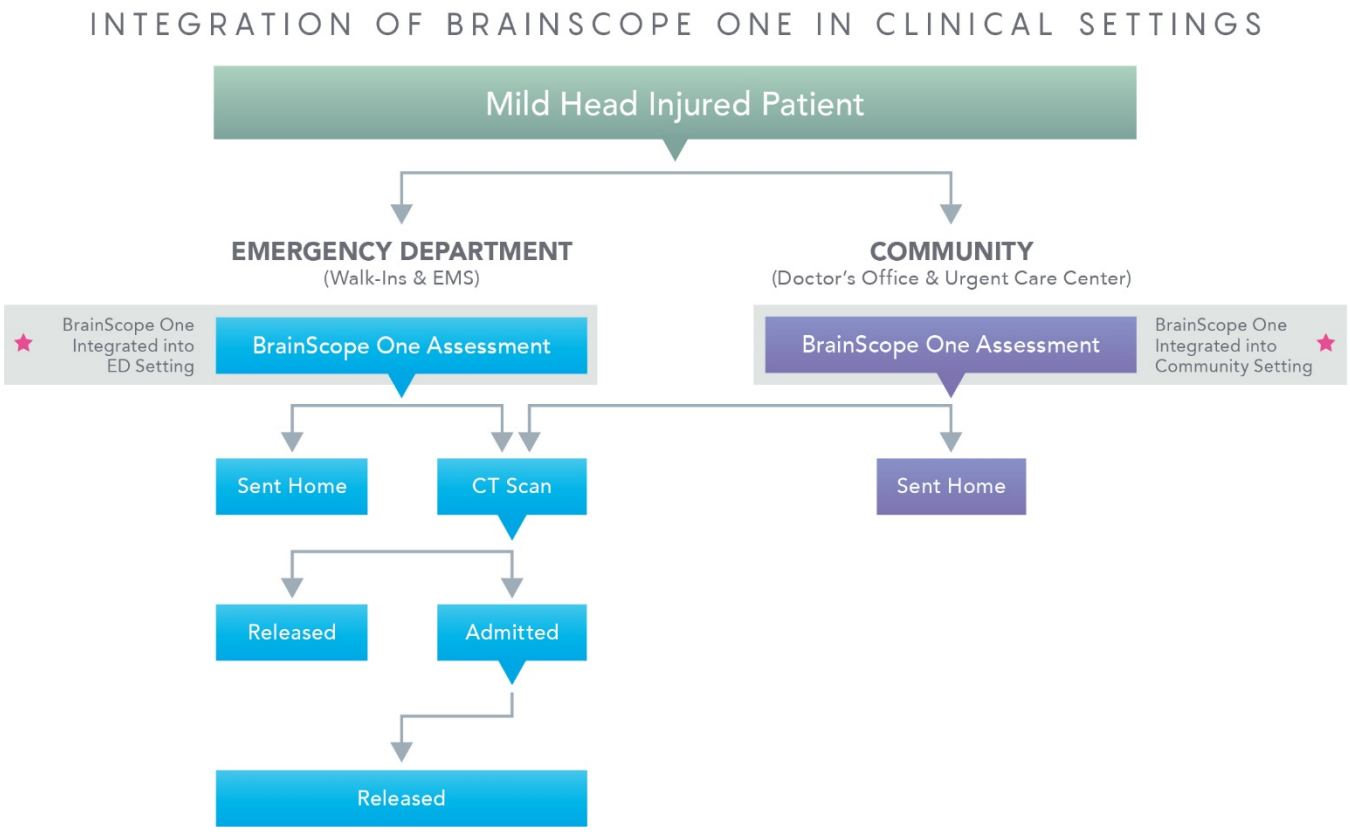

Figure 2: Integration of the *BrainScope One* assessment in the Emergency Department and Community (UCC & Physician's Office) settings.

2.2. Healthcare Pathways for Evaluation of Mild Head Injury

Integration of *BrainScope One* into these settings creates a new treatment pathway for the assessment of mildly presenting head injured patients. By modeling and assessing the differences between this new pathway with *BrainScope One*, and the current clinical pathway, BEAM computes the impact on payer reimbursement associated with the utilization of *BrainScope One*, based on several model inputs, parameters, and estimates. BEAM has the capability to assess an array of all possible routes through the current and new pathways to determine the overall impact of *BrainScope One* by applying frequencies and associated costs at each point in the pathway. Patient choice and provider triage decisions create an extensive array of decision pathways, resulting in relatively complex current and new pathway models.

To demonstrate the differences in the treatment pathways and their associated decision points, a single scenario has been selected as an example. This example pathway represents a mild head injured subject who presents to the ED for assessment and is ultimately determined unlikely to have a structural injury present and is not referred for a CT scan. Figure 3 shows a flow chart for the treatment pathway without *BrainScope One* (Pathway A) and with *BrainScope One* integrated into the assessment (Pathway B).

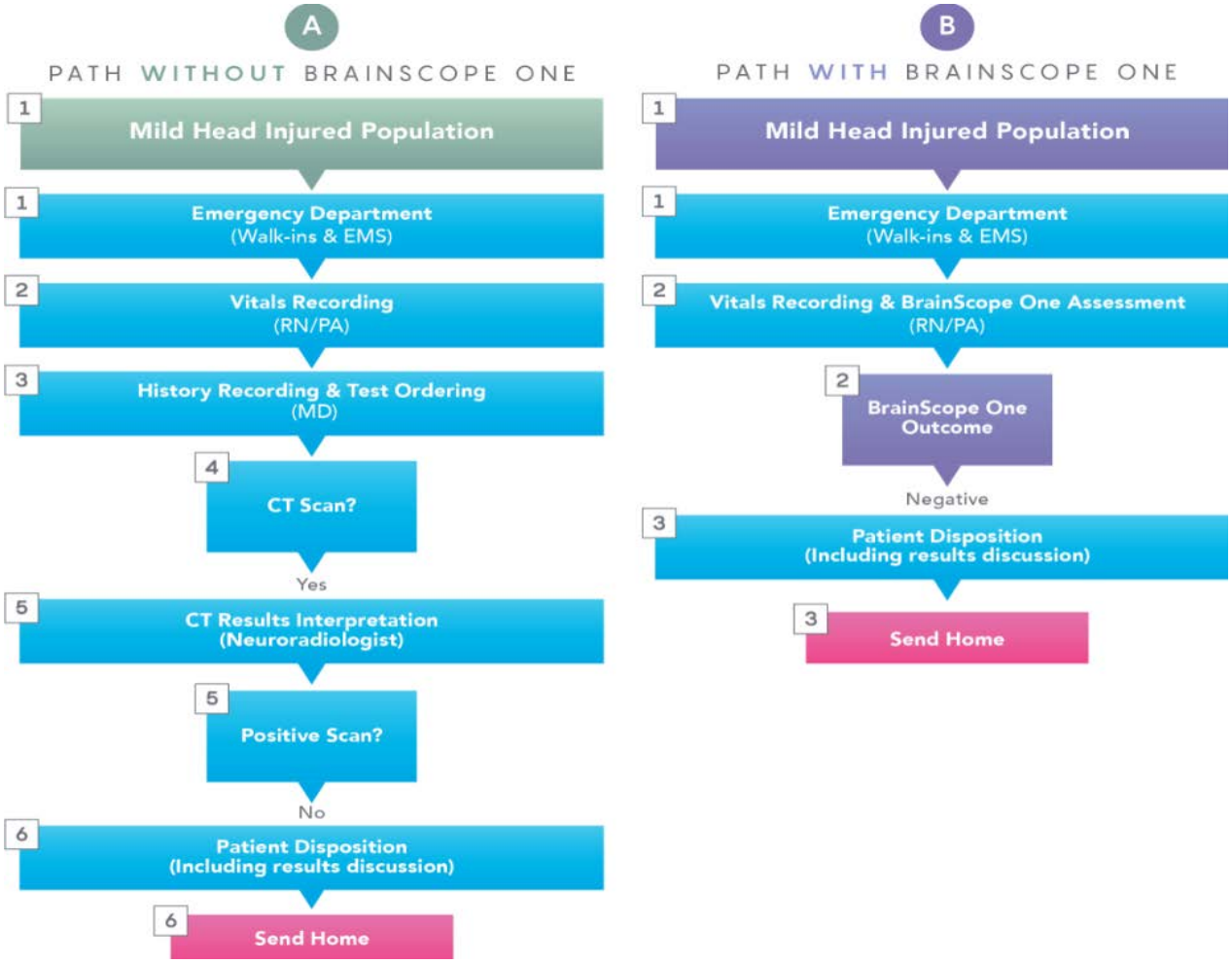

Figure 3: Comparing Panel A (conventional path) to Panel B with integration of *BrainScope One* demonstrates the potential effect of the integration of *BrainScope One* into the mTBI diagnostic treatment pathway.

Table 1: Touchpoints associated with the two pathways, one without *BrainScope One* (left column) and one with *BrainScope One* integrated into the assessment (right column).

PATHWAY **WITHOUT** BRAINSCOPE ONE		PATHWAY **WITH** BRAINSCOPE ONE	
#	Associated Touchpoints	#	Associated Touchpoints
1	Mild Head Injured patient presents at the ED Intake/Registration	1	Mild Head Injured patient presents at the ED Intake/Registration
2	RN/PA conducts vitals recording on patient	2	RN/PA conducts vitals recording on patient; patient meets criteria for BrainsScope One assessment, test is completed; result is Negative for the structural injury classifier
3	ED physician conducts history recording & test ordering, patient meets criteria for CT scan	3	Review of BrainScope One results by ED physician; communication of results to patient; patient is sent home from ED
4	CT scan is conducted		
5	CT results interpretation by Neuroradiologist; result is Negative for structural injury		
6	Review of CT results by ED physcian; communication of results to patient; patient is sent home from ED		

Table 1 describes in more detail each step in the flowchart shown in Figure 3. In the pathway without *BrainScope One*, the mTBI patient is sent for a CT Scan (resulting in additional associated touchpoints), found to be CT Negative, and then released. In the pathway with *BrainScope One* (right panel), the patient receives a *BrainScope One* assessment, the results of which are found to be negative, indicating likely no injury visible on a head CT scan, and this patient is then discharged. While not representative of every mTBI patient scenario, this example represents a high frequency example since 91% of CT scans for TBI are found to be negative.[3] The integration of the *BrainScope One* test in this pathway allows for the diversion of patients who have a high likelihood of receiving an unnecessary CT scan. In addition, availability in the Community setting promotes diversion of patients away from the ED and toward these settings of care, where an ED referral can then be ruled out more confidently with the aid of *BrainScope One*.

2.3 Key Inputs, Parameters, Estimates, and Outputs

BEAM incorporates several inputs, parameters, and estimates into its computation of economic impact (for details see Appendix 1). User inputs allow the model to remain dynamic, making it customizable to the appropriate scenario being assessed. Key inputs available to the model user include:

- *BrainScope One* Penetration (per setting): percentage penetration of the *BrainScope One* test in a specific setting (e.g., UCC).
- Diversion of Emergency Department Walk-ins: penetration of the *BrainScope One* test in the Community will result in the diversion of patients who previously would have gone to the ED to these alternative settings. The user is able to specify a maximum percentage of diversion from the ED to a Community setting, which sets a ceiling for diversions.
    - This value is associated with availability and awareness of *BrainScope One* in the Community setting and is independent of *BrainScope One* assessment results.

To simulate the impact of actual utilization of *BrainScope One* in the ED and Community settings, this analysis leverages BrainScope Registry data on the percent reduction in referrals to the ED due to negative *BrainScope One* assessment results to determining the value for a key model estimate. A value of 75% reflects an optimal, yet realistic, impact on reduction in ED referrals from the community setting based on *BrainScope One* results reported through the national

Registry.[10] To ensure BEAM accurately models real-world outcomes, model parameters are based on values taken from literature, claims experience from the IBM MarketScan® database and actuarial estimates.[12]

This analysis examines the impact on mTBI/ concussion cost savings of varying key inputs of Penetration and Max Diversion of Emergency Department Walk-ins. These inputs are varied in unison to aid interpretability. BEAM uses the identified pathways and associated inputs, parameters, and assumptions to determine frequencies and associated costs at specified points in the pathway. Comparison of these values between the current and future pathways allows the model to calculate the net potential mTBI/concussion cost savings for payers and patients.

3. Results

The impact of penetration of *BrainScope One* on the distribution of patient volumes across settings (ED and Community), coupled with the impact of diversion of ED walk-ins to the Community setting for initial assessment due to availability and awareness of *BrainScope One*, is shown in Table 2.

A positive correlation can be seen between penetration/diversion and the portion of patient volume presenting at Community settings. As penetration across the clinical settings increases and the frequencies shift away from costly ED visits and unnecessary CT scans, BEAM demonstrates the potential for significant savings for mTBI cost.

Using the selected rate of 75% for the reduction in ED referrals from the Community setting due to a negative *BrainScope One* result, BEAM was used to calculate percent savings over an incremental range of penetration and ED Walk-in diversion values. Figure 5 shows the percentage cost savings assuming different penetration and ED-Walk-in rates varying from 10% to 90%. To help interpretability, penetration rates for each setting are varied at the same rate, though they may be varied independently in BEAM.

It can be seen that with a selected rate of 75% for ED referral reduction due to the availability of the *BrainScope One* test in the Community, reductions in charges incurred by patients and payers range from 3.1%-32.2% depending on *BrainScope One* penetration as well as diversion of ED Walk-Ins to the Community setting for initial assessment. The net savings represents cost reduction resulting from the use of *BrainScope One*, taking into account additional cost of administering the test. A detailed breakdown of the source of savings by type of service is provided in Appendix 2.

Table 2: Patient Volumes after Introduction of *Brainscope One*

PENETRATION (ED & COMMUNITY) & MAX DIVERSION OF ED WALK-INS	SETTING			
	Emergency Department		Community	
	Walk-Ins	EMS	Physician's Office	UCC
0%*	91.5%	4.4%	2.2%	1.9%
30%	85.4%	4.4%	4.6%	5.5%
60%	62.5%	4.4%	13.8%	19.3%
90%	19.3%	4.4%	31.0%	45.2%

*Current pathway without BrainScope One

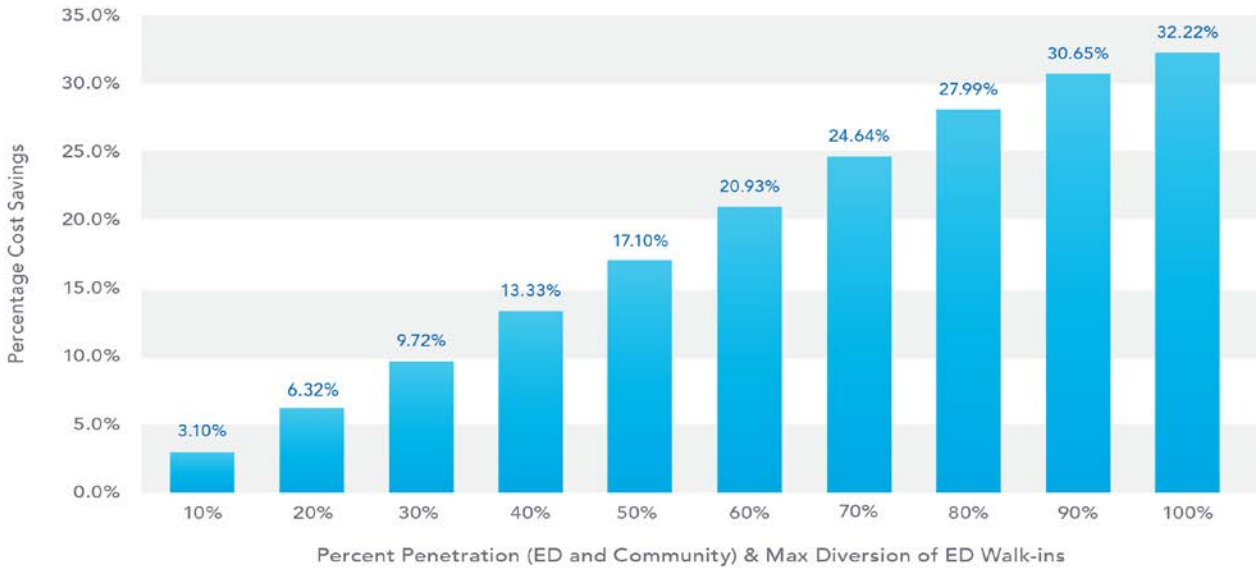

Figure 5: Cost Savings percentage as a function of Penetration and Max Diversion of ER Walk-ins

Discussion and Conclusion

Based on the model assumptions, integration of *BrainScope One* in the ED and Community settings results in a potential significant reduction of charges of up to 32.2%. These results, derived from an actuarial model (BEAM), clearly demonstrate the potential economic impact to healthcare payers and patients that can be realized through the adoption of this easy-to-use, rapid, effective, and objective hand-held medical device. Beyond this financial impact, *BrainScope One*'s integration also facilitates a clinical impact, promoting additional improvements along the patient care pathway.

These broader benefits to the healthcare system associated with *BrainScope One's* integration include *decreased ED overcrowding* by diverting patients and reducing ED referrals; *reduced radiation exposure* by avoiding unnecessary CT Scans; *increased care access points* by integrating device in various patient care settings including rural settings where CT may not be available; *decreased processing time* for non-critical patients by lowering the number of touchpoints during triage, thereby freeing capacity for higher acuity patients; *early intervention* through objective functional injury data; *reduced patient wait times*, increasing productivity and improving patient satisfaction; and *provision of objective* data to aid clinicians in making a more informed and confident decisions to hold patients for observation. These benefits positively impact the collective stakeholders of the healthcare system, including payers, patients, and providers.

BEAM was developed as an actuarial model to specifically analyze the associated costs related to the initial triage of mTBI patients and does not capture additional cost savings implications and potential downstream savings associated with these broader benefits to the healthcare system. BEAM is currently calibrated specifically for a commercially-insured population aged 18-65, using 2016 data from the IBM MarketScan® database and does not account for subsequent inflation or pricing adjustments.[12] Future improvements to the model to address these limitations may provide a more applicable figure for the savings associated with *BrainScope One's* impact on other populations, as well as the broader healthcare system. With this impact accounted for, the already substantial financial savings demonstrated by this model may only represent a portion of the overall savings achievable for the entire system. These savings would drastically lessen the financial and clinical burden to the health care system that stems from short- and long-term consequences of mild traumatic brain injury.

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Judith D. Bentkover, PhD is an educator, author and consultant. As a health economist, Judy is a Professor of the Practice at Brown University's School of Public Health and Tufts University's Economics Department. She has authored several books and peer-reviewed publications about the economic value of specific health care products and procedures. As President of Judith Bentkover & Associates, she regularly consults with global healthcare providers and payers, as well as manufacturers of biopharmaceutical and medical device products.

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Appendices

Appendix 1: Key BEAM Inputs and Parameters

Model Inputs	
Description	**Value Used in Paper**
Population	1,000,000
BrainScope One Penetration- ED	0%-100%
BrainScope One Penetration- Physician's Office	0%-100%
BrainScope One Penetration- UCC	0%-100%
Max Diversion of Emergency Room Walk-ins	0%-100%
Model Parameters	
Description	**Value Used in Paper**
% of ED-bound patients diverted due to Negative BrainScope One	75%
% of CT-bound patients diverted due to Negative BrainScope One	75%
% of Diverted ED Walk-ins to Physician's Office	40%
% of send-homes confirmed via BrainScope One- ED Walk-in	50%
% of send-homes confirmed via BrainScope One- Physician's Office	40%
% of send-homes confirmed via BrainScope One- UC	30%
Cost for CT Scan Cost	$782

Appendix 2: Results Summary and Detailed Breakdown

2.1 Results Summary

	Without Brainscope 1	With Brainscope 1	Savings
Total Annual Cost	$21,368,163	$14,483,429	$6,884,734
Cost Per Case	$1,931	$1,309	$622
Cost PMPM	$1.78	$1.21	$0.57
Savings Percentage			32.22%

2.2 Source of Savings by Type of Service

Type of Service	% of Total Savings	$ Savings
Total		**$6,884,734**
ER Flat Charge & RN/PA vitals recording	66%	$4,510,418
CT Scan	64%	$4,384,957
MD history recording & test ordering	31%	$2,127,622
CT reviews by MD & Radiologist	6%	$435,186
EMS	0%	$0
Inpatient Stay	0%	$0
Observation	0%	$0
MD	-10%	($688,804)
UCC	-15%	($1,033,205)

2.3 Unit Costs and Frequencies of Services for Current and Alternative Pathways

		Without Brainscope 1		With Brainscope 1		
Type of Service	Unit Cost	Count	Total	Count	Total	Savings / (Costs)
EMS	$1,175	490	$575,984	490	$575,984	$0
MD	$170	308	$52,408	4,360	$741,212	($688,804)
UCC	$170	240	$40,802	6,318	$1,074,008	($1,033,205)
ER Flat Charge & RN/PA vitals recording	$610	11,066	$6,752,054	3,674	$2,241,636	$4,510,418
MD history recording & test ordering	$280	11,066	$3,098,482	3,467	$970,861	$2,127,622
CT Scan	$782	9,074	$7,096,719	3,467	$2,711,762	$4,384,957
CT reviews by MD & Radiologist	$78	9,074	$704,316	3,467	$269,130	$435,186
Inpatient Stay	$33,704	90	$3,036,586	90	$3,036,586	$0
Observation	$300	36	$10,811	36	$10,811	$0
Charge to administer BrainScope1: Physician	$350			3,250	$1,137,445	($1,137,445)
Charge to administer BrainScope1: Urgent Care	$350			4,885	$1,709,780	($1,709,780)
Charge to administer BrainScope1: Emerg. Dept.	$59			-44	-$2,603	$2,603
Later Costs on False Negatives	$2,018			3	$6,818	($6,818)
Totals			**$21,368,163**		**$14,483,429**	**$6,884,734**

BrainScope One is intended for patients 18-85 years of age presenting within 72 hours of mild head injury. BrainScope One is not a stand-alone diagnostic nor a replacement for CT scan. Please refer to: www.brainscope.com/products for complete indications.