

Overview:

This document summarizes the current approach to market sizing using data from TQIP, and the provisional results. TQIP (Trauma Quality Improvement Program) was initiated in 2008 by the American College of Surgeons Committee on Trauma. Its aim is to provide risk-adjusted data for the purpose of reducing variability in adult trauma outcomes and offering best practice guidelines to improve trauma care. Contained within TQIP is data regarding the diagnoses of each patient within the database. In 2019 there were 1.05M trauma activations at level one trauma centers reported to TQIP; of these 68.07k had diagnoses that would indicate a need for EndoShunt. At an initial price point of \$6000/unit EndoShunt's market for the initial indications of use in trauma is provisionally estimated to be \$408M.

Pricing Strategy:

Other O.R. procedures for injuries with major complications (MS-DRG 907) is the most common reimbursement code covering patient's major traumatic bleeding in 2019 the National Average Hospital Reimbursement for Inpatient Procedures was \$25,800.

Data Source:

The ACS (American College of Surgeons) TQIP works to elevate the quality of care for trauma patients. ACS receives data from more than 875 participating trauma centers across the US. TQIP collects data from trauma centers, provides feedback about the center's performance, and identifies institutional characteristics that the trauma center staff can implement to improve patient outcomes. Dr. Milad Behbahaninia is investigating the prevalence of the need for endovascular hemorrhage control using EndoShunt and gained access to the Trauma Quality Programs participant use file through the University of South Florida. This file contains a list of ICD-10 diagnostic codes associated with each trauma recorded in the trauma data bank.

Diagnostic codes:

Used for medical claim reporting in all healthcare settings, ICD-10-CM is a standardized classification system of diagnosis codes that represent conditions and diseases, related health problems, abnormal findings, signs and symptoms, injuries, external causes of injuries and diseases, and social circumstances.

Qualifying EndoShunt's Need:

EndoShunt's initial approach to market involves indications of use in the trauma setting for the treatment of injuries of blood vessels at abdominal, lower back, and pelvis level (ICD-10 S35), as well as injuries of the intra-abdominal organs (ICD-10 S36). Additional granularity can be determined from each line of patient data in the trauma database.

Future Work, Confidentialities, and Disclaimer:

These findings are provisional and subject to change. Granularity of the contribution of each ICD-10 sub-code, as well as cost, mortality, and morbidity data will continue to be explored. This data is based on initial count of ICD-10 codes within the 2019 Participant Use File, and has yet to be independently validated. EndoShunt, Dr. Milad Behbahaninia, and University of South Florida, cannot guarantee these results in anyway at this time. All information contained within this

document is confidential and strictly for general communication and discussion. Portions of this document contain information and text from third-party sources.