MIND THE GAP

Addressing the Delay in CMS Reimbursement Following FDA Approval for Medical Devices

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Honor Statement

On my honor as a University of Virginia Student, I have neither given nor received unauthorized aid on this assignment.

Contents

Acronyms

AMA – American Medical Association

CAC – Contractor Advisory Committee

CMS – Centers for Medicare and Medicaid Services

CPT – Current Procedural Terminology

DRG – Diagnosis Related Groups

EAP – Expedited Access Pathway

FDA – Food and Drug Administration

FD&C – Food, Drug and Cosmetic Act

HCPCS – Healthcare Common Procedure Coding System

HHS – Health and Human Services

LCD – Local Coverage Determination

MAC – Medicare Administrative Contractors

NCD – National Coverage Determination

PMA – Premarket Approval

RBRVS – Resource-Based Relative Value Scale

SMDA – Safe Medical Devices Act

Executive Summary

In order for more patients to gain access to effective medical therapies and medical devices like focused ultrasound, changes need to be made to the current system of obtaining Centers for Medicare and Medicaid Services (CMS) reimbursement. The current process of obtaining reimbursement status following Food and Drug Administration (FDA) device approval takes too long and leaves many patients without life-changing medical therapies. While the FDA has made great strides to increase transparency and support manufacturers navigating the approval process, the CMS reimbursement process remains a significant hurdle for making safe and effective devices available to the public. Options to improve the current process include: implement a new process, expand the Parallel Review Program, or amend the Breakthrough Device Program. These alternatives will be evaluated on the risk posed to patients, the ease of implementation, the political feasibility, and the cost effectiveness, and will also be compared to the option of allowing the current process to continue. The majority of these options would help device manufacturers, such as those supported by the Focused Ultrasound Foundation, by offering them a more efficient process to reimbursement, however I recommend amending the Parallel Review Program to include Local Coverage Determinations (LCDs).

Problem Definition

The Centers for Medicare and Medicaid Services' (CMS) reimbursement process for Food and Drug Administration (FDA) approved medical devices takes too long.

In order for more patients to gain access to effective medical therapies through medical devices like focused ultrasound, changes need to be made to the current system of obtaining CMS reimbursement following their FDA device approval. Increasing the number of FDA approved indications that are covered by CMS will greatly increase the number of patients able to receive focused ultrasound treatment, as Medicare covers 60 million people in the United States and acts as an approval benchmark for both Medicaid and the private insurance market (KFF, 2019). There are both regulatory and knowledge barriers that impede the process of gaining CMS reimbursement following FDA approval. The delay in CMS reimbursement impacts the lives of millions of people, potentially depriving patients of focused ultrasound treatments that could prolong or improve the quality of their lives while living with deadly or debilitating disorders.

Impact on Society

Focused ultrasound technology is FDA approved for six clinical indications: essential tremor, Parkinson's disease, benign prostatic hyperplasia, prostate cancer, uterine fibroids, and bone metastases (FUSF, 2019). CMS only offers reimbursement for focused ultrasound used to treat essential tremor and bone metastases. There are millions of people in the US living with the remaining four FDA-approved clinical indications, which are not covered by Medicare, Medicaid, or the majority of private insurers. The cost to society for those living with Parkinson's, benign prostatic hyperplasia, prostate cancer, and uterine fibroids is potentially as high as 100B per year, including lost productivity, medical bills, and other expenditures. Further cost details may be found in the appendix.

For prostate cancer alone, which effects 1 in 9 men in the US at some point in their lives, the average cost of focused ultrasound treatment is 25% lower than a prostatectomy and 64% lower than radiation therapy. More directly, Medicare facility reimbursement is $7,500 for focused ultrasound treatment, compared to $10,000 for a prostatectomy, and $21,000 for radiation therapy. Additionally, on average lost wages due to

time off work for focused ultrasound is only around $270 (2 days of work), compared to a prostatectomy at $8,000 (60 days of work). Overall, focused ultrasound use is associated with an estimated $1B in patient savings over five years; incontinence and other common side effects of surgery are not as severe following focused ultrasound treatment, leading to reduced need to purchase diapers, pads, and other medical products. There is also projected insurance savings of an estimated $6.8B over five years. These savings are due to lower procedure cost, reduced secondary treatments, and fewer patient complications with focused ultrasound.
Other clinical indications lead to similar savings when focused ultrasound treatment is used. Focused ultrasound is an innovative technology that gives health care providers the capability to treat serious disorders while providing a better patient experience at a lower cost than other common treatments (MITA, 2019).

Focused Ultrasound Treatment

Focused ultrasound is a noninvasive, early stage, therapeutic technology with the potential to improve the lives of millions of people with a variety of medical disorders, including Parkinson's disease and prostate cancer (FUSF, 2019). It can be used as an alternative or complementary therapy to surgery, radiation therapy, and drug delivery. There are currently more than 125 clinical indications being studied; six are approved by the FDA for therapeutic use, however Medicare reimbursement is offered for only two.

Focused ultrasound uses a combination of two different technologies to provide precise treatment to patients – focused ultrasound provides the energy needed to treat deep tissues, and magnetic resonance helps identify and target the tissue needing treatment. Magnetic resonance also guides and controls the treatment in real time for the health care professionals conducting the procedure to ensure the effectiveness of the treatment (FUSF, n.d.). Because of the nature of this technology, focused ultrasound treatments are largely performed in an outpatient setting, require no incisions and can produce results with minimal discomfort and complications for patients (FUSF, n.d.).

Treatment using focused ultrasound predominately allows patients faster recovery, a quicker return to normal activities, and fewer side effects. Patients are discharged on the same day as the procedure and are able to go back to work as soon as 2 days post treatment (prostate ablation) to around 2 weeks (essential tremor treatment). This is significantly shorter than the standard treatment. A prostatectomy requires 3-6 days hospitalization following surgery with six weeks of recovery. Deep brain stimulation, which is one of the most well-known and common treatments for essential tremor, requires the placement of electrodes onto the thalamus during surgery. The electrodes are wired to an impulse generator that is implanted under the skin in the chest near the collarbone. There are distinct disadvantages of deep brain stimulation in comparison to focused ultrasound treatment: increased risk of infection from the placement of a foreign object into the body, repeat surgery every surgery every three to five years to replace the generator's battery, and a significantly longer recovery time has once the impulse generator is implanted, it takes another 2-4 weeks for the device to be activated and possibly adjusted and 3-5 weeks before the medications and stimulators are adjusted before a patient can get relief from their symptoms (WebMD, n.d.).

Background

The History of the FDA and Medical Devices in the United States

The FDA is the oldest consumer protection agency in the United States. In 1906, President Roosevelt signed the Pure Food and Drug Act, which created the predecessor of the FDA and prohibited the interstate transport of unlawful food and drugs. The basis of this law was focused on the product label rather than government market approval. In 1938, the Federal Food, Drug, and Cosmetic (FD&C) Act was passed, which is the primary ruling that authorizes the FDA's regulation and oversight of medical products. In 1968, the Radiation Control for Health and Safety Act was passed, which intended to minimize individuals' exposure to electronic radiation and intense magnetic fields. It also created the performance standards and guidelines for medical imaging devices such as ultrasounds, MRIs and x-ray machines. Two years later, President Nixon formed the Cooper Committee which established the risk-based classifications for medical devices and recommended legislation targeted towards medical devices (FDA, 2019).

In 1976, the medical device industry became subject to large legislative changes through the Medical Device Amendments of the FD&C Act. These amendments provided consumers better assurance for the effectiveness and safety of medical devices by creating the classification system for medical devices, established Premarket Approval (PMA) and premarket notification (510(k)), ensured a regulatory pathway for investigational medical devices and patient clinical studies (Investigational Device Exemption). This act also established postmarket requirements on manufacturers such as listing devices with the FDA, good manufacturing practices, reporting adverse events involving medical devices, and also allowed the FDA to ban devices from use (FDA, 2019).

Over the next decades, several more initiatives were passed. The Safe Medical Devices Act (SMDA) was passed in 1990 which improved postmarket observation of devices by requiring the reporting of adverse events involving medical devices in hospitals and other medical facilities and authorized the FDA to require manufacturers to perform their own surveillance on implanted devices that could potentially cause irreparable harm or death to a patient if it fails. This act also gave the FDA more jurisdiction by authorizing them to order device recalls and impose penalties for violating the FD&C Act. It also better defined provisions in the 510(k) program such as substantial equivalence and created the Humanitarian Use Device/Humanitarian Device Exemption programs to encourage manufacturers to create devices that target rare diseases. In 1997, the Food and Drug Administration Modernization Act was passed, which better defined provisions made previously. It created the option for accredited third parties to conduct the premarket review for certain devices, and permitted data to be used from previous studies of an earlier version of a device in premarket applications for a new version of the device. This act also established the De Novo program which allows low to moderate risk novel devices to be classified into lower classes instead of automatically being classified as a high risk (Class III) device (FDA, 2019).

In more recent history, legislation was passed that established further requirements for the medical device industry. In 2007, the Food and Drug Administration Amendments Act required the FDA to establish an identification system for medical devices and require device labels to have a unique identifier. In 2012, the Food and Drug Administration Safety and Innovation Act was passed and created a more direct De Novo pathway and expanded the application of premarket reviews. The 21st Century Cures Act, signed into law in 2016, was designed to bring new innovations to the medical field and accelerate product development in order to reach more patients in need of innovative technology and procedures to improve their health. This law builds upon the FDA's work to incorporate patients' perspectives into the decision making process surrounding medical products (FDA, 2019). It also established new, expedited product development programs including the Breakthrough Devices Program (FDA, n.d.b). In 2017, the Food and

Drug Administration Reauthorization Act was passed and required the FDA to perform at least one pilot project to improve postmarket surveillance of medical devices (FDA, 2019).

510(k) Premarket Approval

A 510(k) is a premarket proposal made to the FDA to show that a "device to be marketed is safe and effective, that is, substantially equivalent, to a legally marketed device" (FDA, n.d.a). Substantial equivalence means that the device is at least as safe and effective as its predecessor. Substantial equivalence is established by reviewing factors such as the intended use, design, delivered, materials used, manufacturing processes, safety, effectiveness, and biocompatibility, as applicable. A device going through 510(k) market approval may not be marketed in the United States until the applicant receives notice that the FDA has deemed the product substantially equivalent to the previous product. If it is denied, an applicant may supplement their 510(k) application with new data, request a classification designation through the De Novo process, or submit a Premarket Approval Application (only for Class III devices) (FDA, n.d.a). 510(k) applications have been steady in recent years with 3,066 applications cleared in 2018.

The Establishment of Centers for Medicare and Medicaid Services (CMS) and The Social Security Act Amendments for Reimbursement

Medicare and Medicaid were passed as Title XVIII and Title XIX of the Social Security Act (SSA). Medicare was created in order to provide hospital and post-hospitalization care, and home health coverage for nearly all Americans over the age of 65. In order to implement Medicare, the Social Security Administration was reorganized, and the Bureau of Health Insurance was established in July of 1965; which was responsible for the development of health insurance policy. Today, CMS is part of the Health and Human Services (HHS) agency. In 1966, Medicare was implemented, and more than 19 million people were enrolled. Multiple sections of the SSA establish the legislative authority of Medicare and Reimbursement. Section 1862 states "No payment may be made under [Medicare] for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member". Additionally, Section 1815 outlines the payment to providers of services, Section 1833 explains the billing code process and the payment of benefits, and Section 1869 defines the determination process and coverage appeals (Social Security Act of 1934, 2020).

The CMS Reimbursement Process

Traditionally, once a medical device is approved for use by the FDA, manufacturers can begin the process to gain reimbursement status through CMS. Coding, coverage and payment are the prongs of CMS reimbursement.

Coding

Obtaining a proper Healthcare Common Procedure Coding System (HCPCS) code is essential for a successful reimbursement strategy. A HCPCS code is the billing code for a product. There are two levels of HCPCS codes, (1) A Level I code comprises of the Current Procedural Terminology (CPT), an alpha-numeric coding system that was created and is maintained by the American Medical Association (AMA) to identify medical services and procedures. (2) A Level II code, maintained by CMS, is used to identify products, supplies, drugs, and medical equipment (Nusgart, 2013). Currently, Level II HCPCS codes represent around 4,000 categories of medical equipment. Coding is where the majority of medical device manufacturers focus their reimbursement strategy analysis for their FDA approved products. Securing a new code does not necessarily mean that CMS will reimburse for the procedure, as there are codes that are assigned a dollar value of zero (Diage, 2015).

The process for obtaining a new CPT code is both time and resource intensive. The CPT editorial panel meets only three times a year according to a published schedule to review coding requests and modifications to existing codes.

Coverage

Coverage is decided through either a National Coverage Decision (NCD) or a Local Coverage Decision (LCD). Coverage is when insurance like Medicare pays health care expenses like treatments, hospital stays, and medication as part of their plan. NCDs are harder to obtain as they require a significant amount of data and only applies to a small number of medical devices; at least one published randomized controlled trial is required. NCDs are determined by CMS only and when approved, apply nationally. NCD's are developed by CMS Central Office/Coverage and Analysis Group and follows required and set timelines that is a lengthy process. The process that results in an NCD begins with a preliminary meeting with the CMS Coverage and Analysis Group to discuss the requirements of the applicant. Then, a benefit category is issued, and a national coverage request is submitted. The national coverage request is published and then there is 30 days to public comments to be submitted. Then if necessary, at this point in the process the application is then sent to the Agency for Healthcare and Research Quality to conduct a technology assessment of the application, and/or is sent to the Medicare Evidence Development & Coverage Advisory Committee for review, the step adds on average another three months to the NCD process. If these two steps are not necessary, then the application is sent to the CMS Analysis staff to review and a draft decision memo is posted. The time elapsed from the initial request to the decision memo is a maximum of six months. After that lengthy process, there is a public comment period of 30 days. After the comment period, comments are taken into consideration and CMS posts their final decision memo and implementation instructions. If there is a positive NCD determination, the application is awarded one of three designations: (1) A full NCD where coverage is generally consistent with FDA intended use, (2) "coverage with evidence development" where CMS finds the technology compelling but needs more evidence, or (3) "coverage left to Medicare Administrative Contractors discretion" which essentially acts as a green light to proceed with obtaining LCDs. If the technology is deemed "not reasonable or necessary" and coverage is not awarded, the applicant can then submit an appeal or be reconsidered when they have more evidence etc. (Avalere Health, 2018).

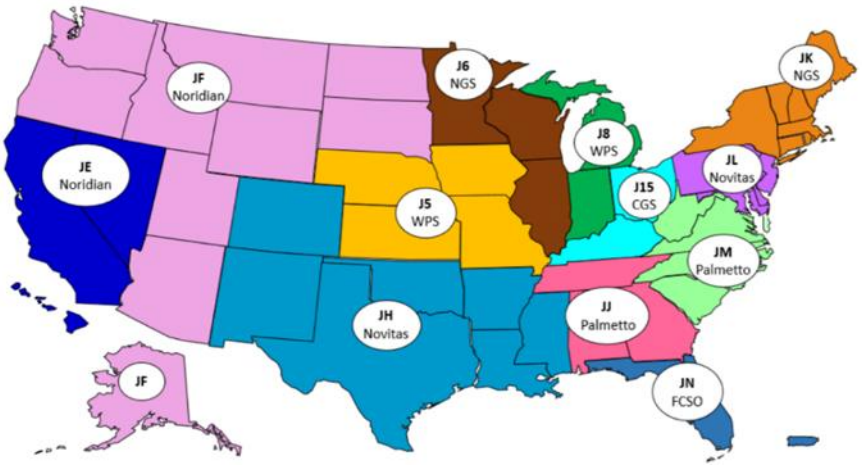

Figure 1: Medicare Administrative Contractor (MAC) Map *Source: CMS, 2019*

In contrast, LCDs are determined by Medicare Administrative Contractors (MACs) and when approved, only apply to the region of the MAC that made the coverage determination. Obtaining an LCD is known to be a more transparent process than obtaining an NCD. There are 12 MACs that serve over 1.5 million healthcare providers. There are no NCD's issued for focused ultrasound. LCDs have been issued by a select number of MACs which limits the coverage to specific areas of the United States (CMS, 2019). MACs follow a formal LCD process that is similar but less complicated than the NCD process. To start, the applicant must meet a threshold of claims, answer provider questions or concerns, and the contractor must address the concern of misuse or over-utilization of the technology. Then the issue regarding the clinical indication and technology is identified, the contractor reviews it and schedules a public meeting.

Within 90-120 days a public meeting is held, this timeline is not mandated by any statutes or policies, but it is the guideline that MACs aim to meet. Once the meeting is held, the issue is presented to the Contractor Advisory Committee (CAC). Then, a draft LCD is developed that is based on local practice and the clinical literature. Next, the MAC posts the draft LCD for public comment including comments from the manufacturers; the comment period is 45 days. After the comment period, the MAC posts the comments and responses to the draft LCD. Once these responses are reviewed typically over another 45 days, the LCD posts the final LCD (Avalere Health, 2018).

MACs must employ a minimum of two Contractor Medical Directors (CMD) per jurisdiction with an appointed alternative for when current CMDs are unavailable. A CMD: must be a clinician currently licensed in the US, cannot be a medical director at a MAC parent company, should be a leader in the provider community, provide clinical expertise in developing LCDs and guidelines to determine if and when LCDs are needed or should be revised. The CMD is also the acting co-chair of their local CAC. Each state has their own CAC that advises the MAC Medical Director on coverage determinations. The CAC is the formal method for providers in a state to contribute in the development of an LCD. This includes discussing administrative policies, exchanging information between carriers and physicians, disseminating proposed LCDs and discussing possible conflicts or inconsistencies in applications. CACs are often comprised of physicians from key clinical specialties and committees at the state level. Specialty societies play an important role in LCD development. CMDs and CACs often consult these specialty societies to provide input on evidence and to provide comments during the comment period. It is important to note that each MAC has different processes and utilize specialty societies differently as well as different key personnel and approaches to determining coverage. Manufacturers need to develop strategies that are tailored to each MAC while ensuring consistency in their application and evidence (Avalere Health, 2018).

Payment

Securing payment is the final hurdle in gaining full CMS reimbursement. Payment is the amount a hospital or provider will be paid for a product. The most common method for calculating this payment is through the Resource-Based Relative Value Scale (RBRVS) which weighs physician's work, practice expense, and professional liability insurance in order to determine the Relative Value Unit (RVU). An RVU is assigned to each CPT/HCPCS by the AMA and is then approved and published by CMS. Additionally, the RVU is modulated based on the geographic location of the provided services. Prior to publishing, these pay rates are made available to the public, as well as private insurers, for comment and analysis. Private insurers can adjust their reimbursement strategy based on the CMS fee schedules. It should be noted that no codes for Focused Ultrasound have undergone the RBRVS analysis. Instead, in the hospital outpatient setting, the most common setting for Focused Ultrasound treatment, Ambulatory Payment Classifications (APCs) are used; payments are established by multiplying an annually updated relative weight for a given service by a similarly updated Conversion Factor. CMS publishes the annual updates to these numbers in the Federal Register each year in November. The weights are given under each CPT code. APCs were created in order to transfer some financial risk for provision of outpatient services from the government to individual hospitals, hopefully leading to cost-savings in the Medicare Program. By transferring financial risk to hospitals, APCs incentivize hospitals to provide outpatient services economically, efficiently and profitably (ACEP, 2019). For Focused Ultrasound, treatment for Essential Tremor is coded as 0398T; however, each provider is responsible for obtaining their own code for billing. In 2016, CMS set the institutional payment for focused ultrasound treatment for essential tremor at approximately $10,000 to be re-evaluated every few years. According to Medicare's procedure price lookup tool, prostate ablation using focused ultrasound costs a total of $1,913 at an ambulatory surgical center with the patient paying only $382. The cost of the same procedure is higher in a hospital outpatient setting with a total cost of $4,020 with the patient paying on average $804 (Medicare, n.d.). These prices do not include physician fees, which can vary

widely and are determined at the MAC level and not posted to CMS' Physician Fee Schedules but the average price of the total procedure is $40,000 (FUSF, 2019).

Medicare's Influence on the Private Insurance Market and other Government Health Insurance Programs

In addition to providing insurance for nearly 60 million Americans, Medicare also plays a large role in the private insurance market. Medicare is often the first insurer to reimburse for new technologies, including drugs and medical devices. This is because private insurers will wait until detailed Medicare and Medicaid reimbursement information from CMS is made available to the public. Private payers will use this information as a benchmark, driving competition between other payers. Cost containment is a large consideration in driving private payer choices to reimburse a device or not (Bruen et al., 2016).

Medicare also contributes to the process of determining the price for most medical treatments and services that are provided in the US. Medicare sets what is considered a "fair price" for the services given to a patient. Since Medicare insures such a large portion of the population, their rates have a substantial impact on what other insurers pay. Research has shown that a $1 change in Medicare reimbursement produces a $1.30 change in what private insurers pay for the same service (Continuum, 2014).

Breakthrough Devices

The Breakthrough Devices Program is an FDA exclusive program that allows for fast-tracking of certain novel devices or device led-combination products (products that are therapeutic and/or diagnostic that combine drugs, devices, or biological products.) The goal of this program is to give health care providers access to devices that provide more effective treatment or diagnosis in a timelier manner so that they can help their patients as best as possible. The program speeds up the development, assessment, and review processes while preserving the FDA's standards of approval. This program replaces the Expedited Access Pathway (EAP) and Priority Review for medical devices programs as the EAP did not include 510(k) applications and the priority review is now limited to drugs (FDA, n.d.b).

The Breakthrough Devices Program offers device manufacturers an opportunity to work directly with the FDA through the premarket review stage of the approval process. Devices that are subject to premarket approval applications, 510(k)s or requests for De Novo designation are eligible for breakthrough device designation if they meet two criteria. (1) The device provides a more effective treatment or diagnosis for a life threatening or debilitating human disease or condition than previous therapies. (2) The device meets at least one of the following: a) represents breakthrough technology, b) no approved or cleared alternatives currently exist, c) provides a significant advantage over current cleared or approved alternatives, d) the device's availability is in the best interest of patients (FDA, n.d.b).

Payor Communication Task Force

The FDA's Center for Devices and Radiological Health evaluates the safety and effectiveness of medical devices in the US. In 2016, this department established the Payor Communication Task Force in order to assist in the communication between device manufacturers and payors to potentially shorten the time between FDA approval and coverage decisions. By initiating communication earlier in the process, manufacturers may design their clinical trials to produce the data required for FDA approval and a positive coverage decision. Payors included in the task force are CMS as well as private plans such as Aetna, Cigna, and Blue Cross Blue Shield. Health technology assessment groups, and other stakeholders who often provide input into the reimbursement process are also welcome to join. This is a voluntary opportunity for medical device manufacturers to obtain payor input in clinical trial design or other strategies for gathering clinical evidence. The decision to participate does not alter the regulatory or evidentiary standards for FDA uses for decision making (FDA, n.d.c).

Parallel Review

In 2011, the FDA and CMS introduced the Parallel Review Program. This program was established through regulation (CMS-3180-N4 and FDA-2010-N-0308) as a way for FDA and CMS to review medical device applications and clinical data and at the same time. This was created to help decrease the time between FDA approval of a pre-market approval application and an NCD through CMS (Federal Register, 2016). This program has two stages: (1) Both FDA and CMS meet with the applicant to provide feedback on clinical data from the pivotal clinical trial as part of their FDA pre-market approval application. (2) FDA and CMS concurrently review the clinical trial results. This review is done independently by both organizations and will separately determine whether the medical device meets their respective requirements and relay their individual determinations (Federal Register, 2016).

Unfortunately, since its inception in 2011, the parallel review process has only approved two products as of 2018. The two devices that were approved through parallel review are diagnostic devices. In December 2017, Tamara Syrek Jensen, Director of Evidence and Analysis at CMS stated that "…a lot that goes on between the agencies outside the formal parallel review process." She also suggested that there are "informal opportunities" for device manufacturers. Specifically, companies that are currently working with the FDA on their clinical trial do not have to wait for approval to begin to obtain CMS's feedback on their product. Companies can informally work with CMS to determine specifications needed for a coverage decision. One criticism of Parallel Review is directed toward the limitation that it only applies to CMS reimbursement through NCDs. Many companies avoid the NCD process and prefer LCD through MACs (Al-Faruque, F, 2018).

Current Legislation

A piece of proposed legislation that can affect medical device regulation and reimbursement is S2326-New Opportunities for Value that Extend Lives (NOVEL) Act of 2019. This bill was introduced in July 2019 and would "amend titles XI and XVIII of the Social Security Act to expedite coding and coverage of 'novel' medical products, and for other purposes". In this case a "novel" product is defined as a drug, biological product or medical device that (1) has not been assigned a HCPCS code and (2) has been designated as a breakthrough therapy or a regenerative advanced therapy under the FDA. The primary focus of the bill is to expedite the coding of novel products and to assign a HCPCS code. The second focus of the bill is to expedite the national coverage determination process with evidence development. This bill will also enhance coordination with the FDA by mandating a public meeting to discuss improvements to the coordination between the FDA and CMS in preparing for the availability of novel products as well as improve the transparency of criteria for Medicare coverage (S.2326, 2019).

Best Practices for Reimbursement

Switzerland

In Switzerland, all medical services or procedures, which are efficient, appropriate and cost-effective, are covered by the Santésuisse (their social health insurance organization) unless challenged by a health insurer (i.e. an individual health insurance provider) and the state's medical examiner. It is recommended that the manufacturer first complete forms to send to the Federal Office of Public Health which will inform the manufacturer whether or not further assessment or appraisals of the device are needed prior to coverage. If additional information is required by the state, the manufacturer must submit more data, typically clinical or economic. Payment in Switzerland depends on the setting. In an outpatient setting, payment is under a tariff system. This is similar to fee-for-service except with a central uniform tariff point system at the federal level, and a state wide point value that is negotiated between providers and private health insurers. Reimbursement for services may be linked to the provider's qualifications. In an inpatient setting, the payment system is significantly more fragmented. There is a uniform federal payment system in which all medical services covered by the social health insurance are reimbursed based on Diagnosis Related

Groups (DRG). The DRG is based on the cost weight multiplied by the base rate. The cost weight is determined federally while the base rate is negotiated at the state level with private insurers. (ISPOR, 2012).

Japan
While the registration of medical devices in Japan is complicated and can take between one and three years, the reimbursement process is streamlined and relatively simple. Almost all medical devices sold in Japan are paid for through Japan's National Health Insurance (NHI). It is actually illegal in nearly all cases for medical devices to be purchased outside of government approved and reimbursed medical devices. There are four reimbursement categories for medical devices: A, B, C, and F. A and B are for already categorized medical devices while C and F are for new technologies and devices. Depending on the device, it is either reimbursed through procedure fees or product categories. Prices are revised every two years based on either "reasonable zone" reductions or the average foreign pricing. "Reasonable zone" reductions are based on the margins that distributors offer to hospitals and clinics for products in a designated category. The government conducts a survey to assess the prices being charged to clinics and hospitals and the resulting margin as a percentage of the current reimbursement rate. Alternatively, average foreign pricing adjustments occur if the reimbursement rate is 1.5 times higher than the average price in the same category in foreign reference countries (the US, UK, AUS, FRA, and GER). Reimbursement only takes nine months following device approval unless you are trying to increase reimbursement by placing a product into a higher reimbursement category which can take more than a year. It is important to note however that positive reimbursement results are more difficult to obtain due to Japan's desire to curb rising health care costs (Pacific Bridge Medical, n.d.).

Cost

The direct costs of successful Medicare reimbursement for FDA approved focused ultrasound medical devices are calculated using the CMS program budget as well as the cost that the AMA incurs from determining the payment scheme and coding. The total direct cost of successful reimbursement is $22,637,024. This number assumes the number of personnel at CMS who work on reimbursement is 50 FTEs and the department runs at a per-employee cost of $421,970 when including benefits, capital investment, rent, and other expenses.

The AMA spends 70M a year maintaining the CPT code list as well as issuing new codes with attachment payment. A large portion of this expense is spent assigning the RBRVS of the CPT/HCPCS code. While none of the CPT/HCPCS codes that are currently assigned to focused ultrasound have been set to an RBRVS scale, this is still as large cost to consider as all codes are maintained by this system.

There is also the overall cost to society that must be considered. The cost to society for those living with the six clinical indications that the FDA has approved focused ultrasound technology for: Parkinson's, benign prostatic hyperplasia, prostate cancer, and uterine fibroids is potentially as high as 100B per year, including lost productivity, medical bills, and other expenditures.

These costs can be seen in more detail in the appendix.

Evaluative Criteria

A set of four criteria will be used to evaluate the proposed policy alternatives. The criteria are cost-effectiveness, political feasibility, ability to implement, and risk. The criteria will be weighted by their importance in the overall success of enacting potential alternatives as well as the certainty of the information that is analyzed.

- **Cost-Effectiveness** is assessing the estimated change in time from FDA approval of a medical device to CMS reimbursement per the dollar amount spent by the federal government. Effectiveness is defined by the decrease in time between FDA approval of a medical device and gaining reimbursement from CMS. Cost is calculated by measuring the financial cost of implementing and administering each alternative. Costs will include cost to implement and administer the alternative. This will include staff, overhead, space and technology. A cost-effectiveness ratio will be determined by the constant discounted rate of 3% over 10 years in dollars divided by the outcome, which is the time elapsed (in months) between FDA approval and CMS reimbursement (Attema et al., 2018).

- **Ease of Implementation** will assess the degree to which each alternative can be implemented successfully. It will take into account the number of agencies or stakeholders involved in the alternative's implementation and the relative interests and priorities that each agency or stakeholder has. Collaboration between agencies, specifically between the FDA and CMS, will be assessed. This will also evaluate the administrative feasibility, including the time required and the complexity of each alternative. This criterion will also assess the scope of each alternative and whether multiple phases are necessary for implementation. The support of additional funds required will also be included in the scoring of this criteria. Scores of "high", "medium", or "low" ease of implementation will be assigned to each alternative evaluated.

- **Risk** will assess the degree to which each alternative will pose risk to patients who receive treatment using medical devices. Some factors considered will include possible changes to the review process, amount of clinical data necessary, and number of stakeholders involved to provide comments. The criterion will weigh the impact of proposed changes on the overall quality of a possibly approved and covered device. Scores of "high", "medium", or "low" risk will be assigned to each alternative evaluated. "High" risk scores will be viewed as the least preferred option for this criterion.

- **Political Feasibility** is the likelihood of the alternative being supported and enacted by Congress. Measuring this criterion involves a comprehensive understanding of the legislative history of CMS reimbursement of medical devices, how similar bills have fared, whether there is bi-partisan support, and why previous bills have failed. This will also examine the existing laws and regulations as well as the committees that oversee Medicare, other HHS programs, and health care in general (see table 1). Additionally, this criterion will weigh the impact of lobbying and industry objectives on the alternative being approved by Congress This criterion will assist the Focused Ultrasound Foundation in developing strategies to navigate Congress with the proposed alternative. Scores of "high", "medium", or "low" political feasibility will be assigned to each alternative evaluated.

Table 1. Congressional Committees

Committee Name	Purpose	Chair	Ranking Member(s)
Senate Finance	This committee, more specifically, the Subcommittee on Healthcare, oversees health programs under the Social Security Act, including Medicare. This committee has sole or shared jurisdiction over the activities of numerous agencies and offices, including the HHS, which includes CMS.	Grassley (R-IA) *Subcommittee on Healthcare:* Toomey (R-PA)	Wyden (D-OR) *Subcommittee on Healthcare*: Stabenow (D-MI)
House Ways and Means	This committee, more specifically, the Subcommittee on Health, handles legislation and oversight related to Medicare. It also oversees the Medicare Trust Fund. Additionally, the subcommittee is involved in payment to hospitals and health care providers delivering care to Medicare beneficiaries, as well as patient out-of-pocket costs and benefits coverage.	Neal (D-MA) *Subcommittee on Health:* Doggett (D-TX)	Brady (R-TX) *Subcommittee on Health:* Nunes (R-CA)
House Energy and Commerce	This committee as a whole has jurisdiction over "health and health facilities (except health care supported by payroll deductions)." Including the FDA.	Pallone (D-NJ) *Subcommittee on Health:* Eshoo (D-CA)	Walden (R-OR) *Subcommittee on Health:* Burgess (R-TX)
House Committee on Science, Space, & Technology	It has jurisdiction over non-defense federal scientific research and development. This committee that considered the 21st Century Cures Act in 2016.	Johnson (D-TX)	Lucas (R-OK)
Senate Committee on Appropriations	These committees have jurisdiction over legislation covering government spending. These committees write legislation that allocates federal funds agencies on an annual basis. This is where other Medicare programs not mandated must be approved from.	Shelby (R-AL) ***Subcommittees*** *Labor, Health, Human Services:* Blunt (R-MO) *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:* Hoeven (R-ND)	Leahy (D-VT) ***Subcommittees*** *Labor, Health, Human Services*: Murray (D-WA) *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:* Jeff Merkley (D-OR)
House Committee on Appropriations	Same jurisdiction as the Senate Committee on Appropriations	Lowey (D-NY) ***Subcommittees*** *Labor, Health, Human Services:* DeLauro (D-CT) *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:* Bishop (D-GA)	Granger (R-TX) ***Subcommittees*** *Labor, Health, Human Services:* Cole (R-OK) *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:* Fortenberry (R-NE)

(Congress.gov, 2020)

Alternatives

Alternative 1: Let the present trends of CMS reimbursement following FDA approval continue

In order to enter the market, medical devices must be approved by the FDA. After approval, manufacturers then pursue obtaining reimbursement through CMS, specifically Medicare. Third party and otherwise private insurers often follow suit, waiting for CMS to make its coverage judgement. This alternative would make no further requests for changes to this process. The Focused Ultrasound Foundation would not need to adjust their current strategy for lobbying for changes to this process. Recently introduced legislation that addresses the problem, including the NOVEL Act of 2019, and further verbal commitment from administrators from the FDA and CMS, lend some hope that this process may become more efficient. This alternative would have Focused Ultrasound Foundation await changes to the process.

Alternative 2: Expand Parallel Review to include Local Coverage Determinations (LCD)

This alternative would expand the parallel review process to cover LCDs, which means that device manufacturers could concurrently obtain FDA approval and regional CMS reimbursement, mitigating the time required to complete the process. One of the biggest criticisms to the Parallel Review process is that it currently only allows for National Coverage Determinations (NCD) by CMS. Many device manufacturers do not utilize the NCD pathway to reimbursement; it is viewed as a gamble because if their application for approval is denied, they must essentially start the process over. This contrasts with applying for an LCD through one of the Medicare Administrative Contractors (MACs), if an application is denied by one MAC, then the manufacturer has the option to apply to a different one. This would require an update to the rule that established the parallel review program (75 FR 57045). This would not require a legislative change. Another potential adjustment within this alternative would be that when one LCD is granted to a treatment, the LCD becomes an NDC the following year if there are no objections by CMS or other MACs. Additional training and education would be required for CMS and FDA personnel but also to inform device manufacturers. Focused Ultrasound Foundation, in partnership with the Medical Imaging & Technology Alliance (MITA), could lobby for LCDs to be included in the Parallel Review process. This would allow the medical device manufacturers that they represent to navigate the regulatory system more effectively (Federal Register, 2016).

Alternative 3: Amend the Breakthrough Device Program to include products that are already in the FDA approval process and to include fast tracking of these devices through the CMS reimbursement application process

The Breakthrough Device Program began in 2019 and is intended to improve timely access to safe and effective medical devices that provide more effective treatment and represent a "breakthrough technology" as determined by the FDA. This year, 97 medical devices received this designation, which fast tracks them through the 510(k) approval process, but does not expedite the CMS reimbursement process (FDA, n.d.b.). This alternative would allow for medical device manufacturers, who products currently in the approval process, to apply for this designation. Additionally, like the parallel review program, this option would bring CMS in at an earlier point to expedite the overall process for patient access. This alternative would involve legislative action by amending section 3051 of the 21st Century Cures Act and section 901 of the FD&C Act which is done through the FDA Reauthorization Act which is not up again until 2022. This alternative would not require any additional personnel or training. The Focused Ultrasound manufacturers that the Focused Ultrasound Foundation supports would be enabled to apply for breakthrough status even if they were already in the midst of the FDA approval process. This, like parallel review, would also allow them to work directly with the FDA and CMS on their applications. The timeframe for this alternative would be relatively minimal as the Breakthrough Device Program is new and

is responsive to feedback about its effectiveness. Additionally, these changes are already in place in the Parallel Review program which would further help expedite this option internally with the FDA and CMS.

Alternative 4: Implement a new process that allows for immediate coverage and reimbursement following FDA approval

This alternative would establish an entirely new process for obtaining reimbursement through CMS and would require a large legislative amendment to the FD&C Act. This would require doing away with the current application process and designating all devices as approved for coverage and reimbursement following FDA approval. Instead of separate application and approval processes that require device manufacturers to apply for (1) a Healthcare Common Procedure Coding System (HCPCS) code, (2) coverage determination, (3) and an approved payment structure, CMS would immediately begin the process of obtaining these for FDA approved devices. CMS would be granted input and a veto during the FDA approval process. This alternative would be similar to Switzerland's model of medical device approval and coverage. This alternative would require the most effort as it would need to be put into law by congress due to the sweeping changes that would be necessary for this new process. This would require a reorganization of personnel and processes which would likely involve the loss of some jobs at CMS for application specialists. This would also require updating the website and ensuring that insurers know how to opt out of a service or device to be covered. In order to accomplish this alternative, Focused ultrasound foundation would need to likely partner with organizations like MITA as well as medical device trade organizations outside of medical imaging in order to more effectively lobby for large structural changes to the current system. The timeline for this option would be the longest of the alternatives listed. This would require coordination and buy-in from other medical device companies and trade organizations in order to educate policymakers and ultimately write and pass legislation. This alternative would require that the FDA and CMS significantly change and update their current processes.

Outcomes Matrix

	Status Quo	**Expand Parallel Review**	**Amend Breakthrough Devices**	**Implement New Process**
Risk (20%)	Low	**Low**	Medium	Medium
Political Feasibility (30%)	High	**High**	Medium	Low
Ease of Implementation (40%)	High	**High**	High	Low
Cost Effectiveness (10%)	$27.9B	**$36B**	$39.9B	$29.3B

Methodology

Evaluation of Risk

Risk assesses the degree to which each alternative will pose risk to patients who receive treatment using medical devices. The status quo poses minimal risk to patients receiving medical treatment through medical devices that are FDA approved and reimbursed by CMS. There is a rigorous application process that manufacturers must go through, including providing a large amount of clinical data, to ensure that the device is safe and effective through the FDA. There is an increased risk to patients posed by alternatives that shorten the application process to FDA approval, the CMS reimbursement process, or both. The alternative of implementing a new process in which CMS automatically reimburses FDA approved medical devices would decrease the amount of rigorous scrutiny that applications undergo compared to the current system; only one agency would review applications instead of at least two. Amending the Breakthrough Device Program would also allow for devices to be approved and reimbursed on less clinical evidence, which could lead to patient harm. For these reasons, both amending the Breakthrough Device Program and implementing a new process were assigned "medium" risk while maintaining the status quo and expanding Parallel Review remained "low" risk to patients.

Evaluation of Political Feasibility

Political feasibility is the likelihood of the alternative being supported and enacted by Congress. Expanding the Parallel Review Program has been assigned "high" political feasibility as it would not require legislative changes. In contrast, expanding parallel review requires a rule change under HHS (75 FR 57045). Amending the Breakthrough Device Program and implementing a new process would require legislation; an amendment would need to be made to both the 21st Century Cures Act and the FDA Reauthorization Act. The 21st Century Cures Act went through the House Committee on Science, Space, & Technology even though this bill proposed many changes to healthcare through the FDA. The original bill had bipartisan support and received a large amount of support from manufacturers and providers, but opponents of the bill said that it would allow devices to be approved on weaker evidence (bypassing randomized control trials), and possibly allow more ineffective treatment to make it to the market. These same opponents would like disapprove of extending that to the CMS reimbursement process. There would also likely be even more opponents to implementing a new process as it would also do away with the review of RCT data by CMS.

Amending the FD&C Act would be required for both implementing a new process and amending the Breakthrough Device Program. The likelihood of an amendment getting passed depends largely on the political climate of that time. The FDA Reauthorization Act is first introduced in the House and is then sent to the House Energy and Commerce Committee which has a subcommittee on Health. The last time the FDA was reauthorized in 2017, it was a very contentious debate even though large portions of it had bipartisan support and both chambers were under Republican control. The timeframe necessary, as well as the uncertainty, makes the political feasibility unclear for two of the alternatives proposed.

Furthermore, private insurers would likely heavily lobby against the implementation of the new process because it would take away their authority to easily deny medical devices that they deem as unreasonable or unnecessary for their patients. Implementing a new process received a rating of "low" with regard to political feasibility due to the sheer amount of obstacles and likely opponents. Amending the Breakthrough

Device Program would be slightly easier as the program already exists and has passed Congress as an FDA only program.

Evaluation of Ease of Implementation

Ease of Implementation assesses the degree to which each alternative can be implemented successfully. Expanding Parallel Review rates "high" in regards to this criterion as it involves the same stakeholders that are currently involved in the process but would bring the MACs in earlier while the manufacturers are still awaiting approval from the FDA. This would require the hiring of more application specialists at each MAC, as well as additional coordination between the MACs and the FDA. There would be multiple phases of implementing this change, possibly rolling out to specific MACs first to test out new processes and hopefully smooth out the implementation process for the remaining MACs. Additionally, a new process of a MAC or CMS to raise an objection to making the LCD of one MAC an NCD would need to be created. The scope of the changes for this alternative are relatively small and do not require sweeping organizational changes. The support of additional funds would likely be approved, as the majority of costs would fall to the MACs as they are private entities contracted by CMS to carry out coverage determinations.

Implementing a new process would be the most difficult alternative to execute which gives it a "low" rating. There would be multiple complex steps to ensuring a successful implementation and the agencies may be reluctant to invest time and energy into this large-scale change; especially if it were to compete with other agency priorities. This would involve doing away with the CMS reimbursement process of approving devices to be "reasonable and necessary" and would solely focus on the FDAs process of deeming a device "safe and effective". This would require a large reorganization of personnel as well as sweeping program changes both at the FDA and CMS. This would also cut MACs largely out of the process as they would no longer be needed to make LCDs. Additionally, the new process would need to be created and executed which requires the hiring and training of new personnel as well as changes to the current IT systems at both agencies. Educating insurers how to opt out of the process would require that either the FDA or CMS publish guidance for private insurers.

Evaluation of Cost Effectiveness

All alternatives considered are more cost effective than the status quo and details of the cost effectiveness calculations can be found in the appendix. With regards to the Parallel Review Program, the two devices that used this process to gain both FDA approval and CMS reimbursement did so in a dramatically shorter timeframe compared to the traditional process. The traditional process of first obtaining FDA approval and then applying for CMS reimbursement (status quo) takes on average 21 months for all medical devices. Focused Ultrasound technologies have taken far above that figure, with an average of nearly 40 months from the initial FDA application to regional CMS reimbursement for essential tremor and tremor dominant Parkinson's indications. One of the two devices approved and reimbursed through Parallel Review, Cologuard, had a total review time of only 16 months (Avalere, 2018). Additionally, the cost of expanding the program in comparison to the status quo is minimal as it only involves introducing the MACs earlier in the process, while the device is still obtaining FDA approval. The cost is the same as the status quo - $22.6M, which gives this alternative a cost effectiveness ratio of $36B.

Expanding the Breakthrough Device Program would have similar changes in regards to effectiveness, the time to reimbursement would decrease, but only if the device is designated as "novel". If focused

ultrasound becomes ubiquitous and multiple devices come to market, then the effect this alternative would have on future devices could be diminished. Additionally, implementing a new system would have a much larger upfront cost, but would effectively decrease the time to reimbursement to equal only the time required to get FDA approval (on average 1 year). Implementing a new process has the greatest cost effectiveness in the long term as it would do away with the CMS reimbursement process almost altogether. The department would be able to dramatically decrease and become more streamlined. The decrease in cost causes this alternative to have the best cost effectiveness ratio of $29.3B

Recommendation

I recommend expanding the Parallel Review Program to include LCDs (Alternative 2). This option is the most politically feasible as it only requires a regulatory change, is cost effective, easy to implement and poses no additional risk to patients. The clinical requirements that are part of the traditional process would stay intact, allowing for a thorough investigation into both the safety and necessity of the device. The key for ensuring that this option is successful when implemented is to build a stronger relationship between stakeholders, specifically the FDA, CMS, and the MACs. Additionally, this would pose minimal to no additional costs from the current process while effectively decreasing the time needed to gain both regional reimbursement to a national reimbursement one year later. An additional recommendation in conjunction with expanding Parallel Review would be to ensure that both CMS and FDA collect and maintain data on this process so that manufacturers can make well informed strategic decisions. This recommendation has the great potential to assist manufacturers with navigating the approval and reimbursement process, as well as increasing access for patients to receive care that will greatly improve their quality of life through treatments like focused ultrasound.

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Appendix – Cost and Cost Effectiveness Analysis

Costs

I. Cost to Society

Table A.1 The cost to society for those living with Parkinson's, benign prostatic hyperplasia, prostate cancer, and uterine fibroids is potentially as high as 100B per year, including lost productivity, medical bills, and other expenditures (Cardozo et al., 2012)(Roehrborn & Black, 2011)(Chung et al., 2016)(Michael J. Fox Foundation, 2019).

Table A.1

Clinical indication	**Cost (per year US)** **2018 Dollars - Billions**
Parkinson's Disease	52
Benign Prostatic Hyperplasia	1.2
Prostate Cancer	12.3
Uterine Fibroids	34.4
Total	**99.9**

II. CMS Budget

a. Total CMS Program Budget 2014

Table A.2 This table shows the total CMS program budget in FY2014 in actual dollars (HHS, 2016).

Table B.2

Program Costs	2014 Actual in Millions ($)
1. Total Personnel Compensation	111
2. Personnel Benefits	28
3. Rental to GSA	17
4. Capital Investment	
Maintain Facilities	6
Equipment	1
Maintain Equipment	5
5. Expenses	
Travel/Transport	5
Supplies	1
Printing	1
Grants	149
Other Goods/Services	65
Advisory and Assistant Services	22
Total CMS Budget	**411**

b. Medicare Per Employee Cost and Average Salary

Table A.3 Shows the Medicare total Program Cost Per Full Time Equivalents (FTEs). This was calculated by dividing the total CMS budget of $411M by the number of FTEs, 974, to get a per employee cost of $421,971. I also took the total personnel composition, $111M, and divided that by the number of FTEs, 974, to get an average salary of $113,963 (HHS, 2016).

Table A.3

FTEs	974
Average Salary	$113,963
Per Employee Cost	$421,971

c. Medicare Reimbursement Cost

Table A.4 shows the cost of the part of the Medicare budget that is used for making coverage and reimbursement decisions and implementation. I made an assumption for this analysis that this number of FTEs would be 50. I multiplied my assumed number of FTEs by the cost per employee of $421,971 to get the reimbursement program budget. These numbers are used for status quo, expanding Parallel Review, and Amending the Breakthrough Device Program.

Table A.4

FTEs	50
Per Employee Cost	$421,971
Assumed Coverage Determination Cost	$21,098,562

d. Medicare Reimbursement Cost for Implementing a New Process (Alternative 4)

Table A.5 shows the cost of the Medicare budget that is used for ensuring reimbursement implementation under the new process that does away with coverage decisions. Coding and payment would still need to be assigned to the device so I assumed a decrease of FTEs from 50 to 10.

Table A.5

FTEs	10
Per Employee Cost	$421,971
Assumed Coverage Determination Cost	$4,219,712

III. American Medical Association (AMA) – CPT Code Maintenance and Resource Based Relative Value Scale (RBRVS)

Table A.6 shows the AMA budget that maintains CPT codes and the RBRVS. The total AMA budget is $70M. In 2019, the AMA added 182 CPT codes which gives a cost per new CPT code of $384,615 (70,000,000/182). There are four clinical indications for focused ultrasound that are FDA approved but do not have a CPT code or RBRVS value assigned to them. This would cost $1,538,461 (384,615 * 4).

Table A.6

AMA Budget for CPT Code and Resource Based Relative Value Scale (RBRVS) Maintenance Per Year	70M
CPT Codes added in 2019	182
Budget Per New Code 2019	$384,615
AMA Budget for Focused Ultrasound FDA Approved Clinical Indications	$1,538,461

Outcomes

Table A.7 Shows the outcome, which is used as part the denominator in the cost-effectiveness ratio. The average time for the status quo was determining the average number of months that it took device manufacturers to gain regional CMS reimbursement for a focused ultrasound devices approved for use for essential tremor. The parallel review assumption was made based on a case study of Cologuard, a colon cancer diagnostic device that was approved through the parallel review program. Cologuard was approved for a NCD in nine months (Avalere, 2018). Amending the Breakthrough Device Program was assumed to be 12 months from FDA approval to CMS approval based on similar programs and devices who have already received breakthrough device designation. Finally, the assumption of two months for implementing a process was given because while the vast majority of the current process would no longer be applicable, coding and payment would still need to be determined, set up, and published.

Table A.7

Alternative	Months From FDA Approval to CMS Reimbursement	Assumption/Notes
Status Quo	40	FUS LCD Reimbursement Average for essential tremor
Expand Parallel Review	9	Assumption from Cologuard case study
Amend Breakthrough Device	12	Assumption based similar on programs
Implement New Process	2	No CMS Reimbursement Needed - Implementation Only

Cost Effectiveness Analysis - Costs

I. Status Quo, Expand Parallel Review, and Amend Breakthrough Device Program

Tables A.8 and A.9 Shows the cost of status quo, expanding parallel review, and amending the breakthrough device program over ten years. There is an assumed 5.5% rise in health care costs per year as indicated by the Congressional Budget Office (CBO) (CBO, 2016). Additionally, a discount rate of 3% is applied to the analysis which is the recommended discount rate for healthcare (Attema et al., 2018)

Table A.8

	Year 1	Year 2	Year 3	Year 4	Year 5
CMS Reimbursement Total Cost	$21,098,562	$22,258,983	$23,483,227	$24,774,805	$26,137,419
AMA Cost	$1,538,461	$1,623,076	$1,712,346	$1,806,525	$1,905,884
Cost to Society	$100,000,000,000	$105,500,000,000	$111,302,500,000	$117,424,137,500	$123,882,465,062
Total Internal (AMA, CMS)	$22,637,024	$23,882,060	$25,195,573	$26,581,330	$28,043,303
Total with Cost to Society	$100,022,637,024	$105,523,882,060	$111,327,695,573	$117,450,718,830	$123,910,508,366
Total Cost to Society with Discount Rate	$100,022,637,024	$102,450,370,932	$104,937,030,421	$107,484,045,722	$110,092,881,783

Table A.9

	Year 6	Year 7	Year 8	Year 9	Year 10	Total
CMS Reimbursement Total Cost	$27,574,977	$29,091,601	$30,691,639	$32,379,679	$34,160,561	**$271,651,458**
AMA Cost	$2,010,707	$2,121,296	$2,237,967	$2,361,056	$2,490,914	**$19,808,236**
Cost to Society	$130,696,000,640	$137,884,280,676	$145,467,916,113	$153,468,651,499	$161,909,427,332	**$1,287,535,378,824**
Total Internal (AMA, CMS)	$29,585,685	$31,212,897	$32,929,607	$34,740,735	$36,651,476	**$291,459,694**
Total with Cost to Society	$130,725,586,326	$137,915,493,574	$145,500,845,720	$153,503,392,235	$161,946,078,808	**$1,287,826,838,519**
Total Cost to Society with Discount Rate	$112,765,039,108	$115,502,054,621	$118,305,502,548	$121,176,995,329	$124,118,184,536	**$1,116,854,742,028**

II. Implement a New Process

Tables A.10 and A.11 Shows the cost of implementing a new process over ten years. There is an assumed 5.5% rise in health care costs per year as indicated by CBO (CBO, 2016). Additionally, a discount rate of 3% is applied to the analysis which is the recommended discount rate for healthcare (CITE).

Table A.10

	Year 1	Year 2	Year 3	Year 4	Year 5
CMS Reimbursement Total Cost	$4,219,712	$4,451,796	$4,696,645	$4,954,961	$5,227,483
AMA Cost	$1,538,461	$1,623,076	$1,712,346	$1,806,525	$1,905,884
Cost to Society	$100,000,000,000	$105,500,000,000	$111,302,500,000	$117,424,137,500	$123,882,465,062
Total Internal (AMA, CMS)	$5,758,174	$6,074,873	$6,408,991	$6,761,486	$7,133,367
Total with Cost to Society	$100,005,758,174	$105,506,074,873	$111,308,908,991	$117,430,898,986	$123,889,598,430
Total Cost to Society with Discount Rate	$100,005,758,174	$102,433,082,401	$104,919,322,265	$107,465,907,757	$110,074,303,576

Table A.11

	Year 6	Year 7	Year 8	Year 9	Year 10	Total
CMS Reimbursement Total Cost	$5,514,995	$5,818,320	$6,138,327	$6,475,935	$6,832,112	**$54,330,291**
AMA Cost	$2,010,707	$2,121,296	$2,237,967	$2,361,056	$2,490,914	**$19,808,236**
Cost to Society	$130,696,000,640	$137,884,280,676	$145,467,916,113	$153,468,651,499	$161,909,427,332	**$1,287,535,378,824**
Total Internal (AMA, CMS)	$7,525,703	$7,939,616	$8,376,295	$8,836,992	$9,323,026	**$74,138,528**
Total with Cost to Society	$130,703,526,344	$137,892,220,293	$145,476,292,409	$153,477,488,491	$161,918,750,358	**$1,287,609,517,352**
Total Cost to Society with Discount Rate	$112,746,009,974	$115,482,563,614	$118,285,538,459	$121,156,546,674	$124,097,239,555	**$1,116,666,272,454**

Determining the Cost Effectiveness Ratio

Table A.12 shows the cost effectiveness ratio. This was calculated by dividing the total cost of each alternative by the units of increased effectiveness (outcome) in relation to the baseline (i.e. the status quo.) Because the status quo is used as the baseline measurement, this alternative has no cost effective measurement. However, the $2.5B serves as the comparator for the other alternatives. For example – the cost effectiveness ratio for expanding parallel review is determined by dividing the total cost over ten years with the discount rate of 3%, $1,116,854,742,028, by the change in the outcome from the status quo, 31 (40 months – 9 months).

Table A.12

Status Quo	$27,921,368,550
Expand Parallel Review	$36,027,572,323
Amend Breakthrough	$39,887,669,358
Implement a New Process	$29,385,954,538