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Improving Health Outcomes for People with Epilepsy in Colorado

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Client Overview

The Epilepsy Foundation of Colorado seeks to improve the quality of life for those with epilepsy living in Colorado. They engage in education campaigns to increase awareness among citizens and healthcare professionals. They also provide some direct assistance to those suffering with epilepsy in the form of informational resources, but they do not directly provide any direct care. Finally, the Epilepsy Foundation of Colorado also seeks to improve care for those with epilepsy receive by providing information to actors in the state government.

Disclaimer

The author conducted this study as part of the program of professional education at the Frank Batten School of Leadership and Public Policy, University of Virginia. This paper is submitted in partial fulfillment of the course requirements for the Master of Public Policy degree. The judgments and conclusions are solely those of the author, and are not necessarily endorsed by the Batten School, by the University of Virginia, or by any other agency.

Honor Statement

On my honor as a student, I have neither given nor received unauthorized aid on this assignment.

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Executive Summary

Epilepsy is both a more common and more dangerous condition than it is commonly understood to be. In Colorado, around 57,000 people have active epilepsy. 56 percent of people with epilepsy continue to have uncontrolled seizures, as many do not receive effective care. Access issues and other barriers to effective care create substantial health risks for people with epilepsy. In many cases, step therapy practices delay certain medications and treatments at the expense of patient health. Step therapy often requires patients try cheaper medication and visit specialists before receiving their preferred treatment. Addressing step therapy requirements and improving access to specialists have the potential to greatly improve health outcomes for people with epilepsy in Colorado.

This report evaluates three potential policy options across three criteria: cost-effectiveness, political feasibility, and administrative feasibility. The policy alternatives are as follows:

1. Prohibit step therapy practices by private insurance companies
2. Add exemptions to step therapy practices for people with epilepsy
3. Fund telemedicine programs for specialist consultations

This report recommends that the Colorado state legislature **adds exemptions based on projected effectiveness to step therapy practices for people with epilepsy**. This alternative is the most cost-effective, costing the least amount of money per person with epilepsy who no longer experiences seizures. There are some predictable challenges that decrease this policy's political feasibility and administrative feasibility. Namely, insurance companies will likely oppose these changes and will be required to expand their exemption processing if this policy is passed. Nevertheless, this policy is both effective and feasible. Actions taken throughout the implementation of this alternative can help mitigate expected and unexpected roadblocks.

Problem Statement

Too many Colorado residents with epilepsy do not receive effective care.

Colorado is estimated to have nearly 57,000 active cases of epilepsy (CDC, 2020). For those with epilepsy, the most severe effect is the risk of death. There are 1.16 cases of sudden unexpected death in epilepsy (SUDEP) for every 1,000 cases of epilepsy every year (CDC, 2020). Often these deaths are a direct result of uncontrolled or frequent seizures. Years of living with epilepsy, seizures starting at a young age, and missed doses of medication also cause SUDEP (CDC, 2020). 56 percent of people with epilepsy still have seizures, putting them at high risk of SUDEP and other health consequences (Tian, 2018).

Increased access to epilepsy medication and healthcare networks can help mitigate these causes. While epilepsy medication is far from perfect, medication reduces seizures for people with epilepsy (PWE) and helps them control their condition. Improving the accessibility of anti-epileptic drugs and epilepsy specialists also decreases medication non-adherence and incorrect dosing. Better access to medication and specialists can help save lives and improve quality of life for tens of thousands of Coloradans.

Background

The CDC estimates that there are about 3.4 million cases of active epilepsy in the United States, making up 1.2% of the total population (CDC, 2020). Colorado accounts for nearly 57,000 active cases of epilepsy. Active epilepsy is defined as people who are taking medication to control epilepsy or who have had at least one seizure in the past year. The widespread prevalence of epilepsy poses a significant economic burden on the US economy, but also has extreme quality of life implications for those with epilepsy.

People with epilepsy require significant medical care. Many epileptics, even those with access to medical care, face uncontrollable seizures. Private insurance companies, Medicare, and Medicaid provide those with epilepsy coverage. The rules and regulations for private insurance companies and public insurance are generally separate. State governments have leeway over the implementation of Medicaid in their state (Nathan, 2017). Funding for these programs is shared between federal and state governments (Altman & Morgan, 2017). State governments can change how Medicaid and private insurance are administered in their state. Medicaid changes tend to be orchestrated through the bureaucracy, while additional regulations on private insurers generally originate in the legislative branch or the office of the insurance commissioner. Changes on the scale of those proposed in this report have historically been passed through legislature. *Given the different baseline policies and means of changing policy between public and private insurance, private insurance will be the sole focus of this analysis.*

Quality of life implications of epilepsy

Beyond direct health risks, people with epilepsy face additional difficulties resulting from uncontrolled or unpredictable seizures. People with epilepsy (PWE) are much more likely to be unemployed. In a 2008 study across nineteen states, adults with active epilepsy had an unemployment rate of 9.8% versus 5.4% for those without a history of epilepsy, meaning they are almost twice as likely to be unemployed (Kobau et al., 2008).

Discrepancies in income are even more substantial. 47.7 percent of adults with active epilepsy reported an annual household income of less than $25,000 as opposed to 26.5 percent of adults without epilepsy falling into that category (Kobau et al., 2008). Not only are PWE more likely to be unemployed, but they also make significantly less income when employed. It is important to note that these are associations. Epilepsy is likely not exclusively the reason for the differences in income. There may be other factors also influencing the income discrepancies.

Low average income in tandem with higher healthcare costs imposes a massive burden on PWE. This is one of the factors that causes medication non-adherence and dosage skipping among PWE. The financial burden of epilepsy paired with a lower income degrades the quality of life

for PWE beyond the direct effects of epilepsy itself. Significantly more PWE reported not seeing a doctor in the past 12 months due to cost in comparison to those without epilepsy (Kobau et al., 2008). This is especially worrying given the importance of doctor visits to obtaining effective care for those with epilepsy.

Epilepsy also affects the mental health of those suffering with it. PWE report higher rates of depression. PWE are three times as likely to say they are dissatisfied or very dissatisfied with life than those without epilepsy (Kobau et al., 2008). Similarly, they report rarely or never getting the emotional support they needed at much higher rates. This translates into mentally unhealthy days, where PWE report having on average 9.3 days a year as opposed to 3.4 for people without epilepsy. Overall unhealthy days, including physically unhealthy days, display a stark contrast of 15.1 days per year for those with epilepsy versus 6.1 days for those without epilepsy (Kobau et al., 2008).

These important discrepancies have a few key negative effects. First, they indicate a substantially lower quality of life for PWE. Second, they explain why PWE are less likely to be employed and, on average, have substantially lower incomes. Higher rates of absenteeism are understandably not preferable for many companies. Third, these differences generate a large cost to society due to lost productivity and work hours. Uncontrolled epilepsy hurts both those with epilepsy and society in general. Improving access to medication for those with epilepsy should help mitigate the negative effects of epilepsy and shrink a number of these differences in key quality of life metrics.

Costs of epilepsy

Direct Costs

There are about 3.4 million cases of epilepsy in the USA (AJMC, 2020). Approximately 56,800 of those cases are in Colorado (CDC, 2020). As such, Colorado makes up 1.67% of national cases. About 56% of people with epilepsy continue to have seizures, which cause increased medical expenses. Nationally in 2014, epilepsy led to 1 million emergency department visits and 280,000 hospital admissions averaging 3.6 days (AJMC, 2020). The estimated total costs of epilepsy were about $28 billion for the entire United States, with outpatient and inpatient comprising the majority of the costs (AJMC, 2020). Directly scaled, the epilepsy costs in Colorado are approximately $467 million annually. This value is an accumulation of medical costs, including the cost of medication, treatment, and hospitalization.

Studies evaluating the costs of epilepsy generally control for the incidence of other diseases. People with epilepsy have higher baseline comorbidities. However, there have been estimates of additional costs for the comorbidities, such as depression, that PWE face. People with epilepsy have significantly more annual mental health costs. Their costs are on average $643 higher per

year (Ivanova et al., 2010). Scaled to Colorado, this would substantiate $37 million in additional costs.

An additional direct cost would be car crashes due to epilepsy. The frequency of these events is uncertain due to inconsistent documentation of crashes. This value is often underestimated, but is still most likely unsubstantial in comparison to other costs (AJMC, 2010). There are also fewer crashes due to epilepsy because PWE are often not permitted to drive. This generates an opportunity cost for those people, but not additional direct costs. Because of the relative insignificance of these costs, they are not generally estimated. Aggregating the direct costs generates an estimate of $504 million of annual costs to Colorado.

Opportunity Costs

Epilepsy has quality of life implications beyond its direct costs. People with a history of epilepsy are more likely to be unemployed and have a lower average annual income. The burdens to quality of life increase with the frequency of seizures. People affected by epilepsy report lower health utility scores, more often attending work while not being mentally or physically capable to work, and higher rates of overall work and activity impairment (AJMC, 2020).

Absenteeism includes both disability and medical related absenteeism. Reductions in work hours resulting from emergencies and non-emergencies are included. Absenteeism related costs were on average $1950 more for those with epilepsy (AJMC, 2010). Other studies have also estimated total indirect costs per patient to be around $2000 more (Ivanova et al., 2010). Scaled to the prevalence of epilepsy in Colorado, these costs would amount to approximately $111 million.

Drivers licenses are often restricted for those with seizures. Approximately 36% of people with epilepsy are not viable for a driver's license, limiting their work and education opportunities (AJMC, 2020). All of these costs are harder to quantify. The inability to drive is heavily linked to the other opportunity costs, such as absenteeism and reductions in work hours by transportation.

Many issues, including those listed above, stem from unmet needs. Medication may never be effective. Alternatively, those recently diagnosed often face difficulty acquiring appropriate and effective medication. This gap between diagnosis and treatment equates to lower health outcomes, but also exacerbates the opportunity costs for these patients.

While there are a number of areas that could be looked into further, studies first focus on direct costs, with only a few expanding to indirect costs. These studies have deemed the costs of absenteeism to be the most significant by far. Subsequently, only these costs are generally estimated. Absenteeism encompasses a number of these issues relatively well, which is why it is used as the catchall indirect cost.

Total Cost

For Colorado, the total costs to society from epilepsy amount to approximately $615 million annually. This value is found by adding $504 million of direct costs and $111 million of opportunity costs. While only a few factors are considered for both the direct and indirect costs, they are by far the most significant within those categories. Medical costs make up nearly all of the direct costs faced. Absenteeism captures nearly all of the indirect/opportunity costs faced. The effects of epilepsy can be estimated in dollar values; aggregating those estimates generates an overall estimate the total cost to society from epilepsy. This overall value gives scale to the economic impact of epilepsy in Colorado, but it does not provide much practical importance. Strategies to improve care for people with epilepsy have the potential to reduce overall costs to society by decreasing the direct or opportunity costs of epilepsy.

Contributing factors to the problem

Step therapy and its consequences

Step therapy is a policy of insurance providers that requires patients to try lower-cost or less preferred medications before gaining access to more preferred medication (Schultz, 2020). Even if a doctor recommends a specific medication, step therapy prevents patients from accessing the medication before completing the previous steps. These steps can take the form of expert consultations or failed attempts with other medication. If patients switch between insurance companies, they are often required to repeat the steps they have completed previously (Givens, 2020). Step therapy has been proven to delay effective care and create unnecessary risk (Givens, 2020).

For people suffering from arthritis, step therapy is also a large concern. The information from these patients is helpful in understanding the effects of step therapy and how they translate to PWE. Over half of patients tried two or more medications before getting the medication their doctor ordered. In 20% of cases, step therapy caused worsening conditions. Nearly 40% of cases had ineffective medication (Givens, 2020). While these statistics are not specific to epilepsy, they provide context on the size and scope of the issue. General medication for epilepsy is thought to be less effective than specialty medication (Givens, 2020).

A common “step” to accessing care is specialist consultations. Rural and underserved populations face specific difficulties fulfilling this step of the process. This creates disproportionate delays in care for vulnerable populations, causing an unnecessary decrease in quality of care and increase in risk (Liverman et al., 2012). While telemedicine strategies address the shortage of specialists, another approach is to remove these requirements, even if only for people in rural or underserved populations. There are concerns about the feasibility of telemedicine, as well as physicians’ willingness to partake in that service (Liverman et al., 2012).

While PWE still need access to specialists, requiring specialist consultations to access necessary medication creates significant delays in care (Liverman et al., 2012).

Effectiveness of medication

Generic medicine is often not as trustworthy or effective in the treatment of epilepsy (Liverman et al., 2012). Early studies suggest that newer generation medications improve health outcomes compared to old generation drugs. Specialty epilepsy drugs have been found to decrease risks of hospitalization from seizures by 31% compared to old generation medication (Faught et al., 2015). However, newer generation drugs are, on average, at least double the price of old generation medication (Holland & Jewell, 2020). While this area could use more research, studies indicate that generic medication is not as effective. Clear metrics and research into the effectiveness of specialty drugs are required to evaluate the implications of policy and make policy decisions (Liverman et al., 2012).

Medication non-adherence

Anti-epileptic drugs are not effective if used improperly. Non-adherence to anti-epileptic drugs (AED) is a major factor in treatment failure and higher mortality rates among PWE (Kai Xuan Teh et al., 2020). Significant non-adherence to medication within epilepsy populations varies between 26% and 79% (Malek et al., 2017). Non-adherence is directly related with additional healthcare costs and indirectly related to decreases in quality of live for PWE (Malek et al., 2017).

The variation in these studies is generally a result of differences in classification and population heterogeneity (Malek et al., 2017). While the variation is initially worrying, differing definitions of what qualifies as medication non-adherence drive much of the variation. Finding good samples for these studies also presents a large difficulty; these studies do their best to address heterogeneity, but cannot completely wipe it from the sample. Their findings should be used as an indication of the problem and effective solutions. Making assumptions based on the specific rates of non-adherence would open up analysis to substantial risk.

Predictors of non-adherence are generally reliable. Perceived access to pharmacy services is a good overarching predictor of non-adherence. Populations which are generally underserved in the health care arena see higher rates of non-adherence to anti-epileptic drugs (Kai Xuan Teh et al., 2020).

Figure 1: Predictors of medication non-adherence among PWE by indicator type

DEMOGRAPHIC	CLINICAL
Younger age	Concerns about side effects of AEDs
Men	Perceived lack of benefit
Lower socioeconomic status	Perceived epilepsy-related stigma
Lower educational attainment	Being seizure free for a time period
Employment status	Multiple comorbidities
	Effective doctor patient communication
	Complicated AED regimens
	Duration of illness

Source: Malek, Heath, and Green 2017

Figure 1 lists key predictors of medication non-adherence. Increased visits with doctors can mitigate many of these factors. Doctors are able to identify and address potential causes of non-adherence when they have frequent visits with patients. Specialists that are aware of these demographic and clinical indicators help improve health outcomes for their patients (Malek et al., 2017).

Simplifying drug dosing can increase medication adherence. Reducing the frequency of doses (from multiple times a day to once or twice a day) improves adherence rates (Malek et al., 2017). Providing more support to PWE through increased contact also reinforces adherence. Decreasing the time between clinical visits increased adherence by 33% in one study (Malek et al., 2017).

Rising medication costs also impact medication non-adherence rates. Patients with deductibles are 41% more likely to abandon treatment (Brownlie, 2020). Deductibles are growing faster than wages. Deductibles have grown 11x faster than inflation in recent years for those with private insurance (Brownlie, 2020). Copayments have also been shrinking, meaning patients have been paying more for services (Brownlie, 2020). Patients with copayment costs are also more likely to abandon treatment.

By shifting away from copayment plans, the greater use of deductibles and coinsurance has pushed more costs onto patients (Brownlie, 2020). Colorado sees higher than average spending by patients due to the deductible and copay structure of plans in the state. Annual out of pocket costs for those with specialty medications on copay plans are about $7000 (Brownlie, 2020). While costs have been increasing, quality of care for patients has not significantly improved.

These are all areas where specialists can be extremely useful. Specialists are able to explain the importance of correct dosing and identify signs of medication non-adherence. Studies have found

that specialists generally improve health outcomes by improving medication adherence rates (Malek et al., 2017). People with epilepsy, on average, see better health outcomes when regularly seeing specialists. Telemedicine can offer a means to make specialists more affordable and accessible.

Access to services

PWE in rural areas struggle to receive the requisite support for their condition. There is a lack of healthcare options in rural and poorer areas, especially when it comes to specialists for diseases such as epilepsy. Telemedicine can break barriers to access for this population, providing services and education key to quality care for PWE (Kissani et al., 2020). In a study of telemedicine services, 81% of families felt they had received clear support and information on their child's epilepsy (Fortini et al., 2020). These virtual consultations result in less work and school time lost, less travel time and cost, better access to medication, and more regular follow-up consultations (Fortini et al., 2020).

The benefits of telemedicine are especially fruitful given the COVID pandemic. The pandemic has exacerbated existing gaps in services, further disadvantaging low income and rural citizens from receiving care (Lavin et al., 2020). This is especially true when it comes to specialist consults, which are much more necessary for people with epilepsy than the average person. Telemedicine bridges the gap in services in a cost efficient manner (Lavin et al., 2020).

Studies on telemedicine offer encouraging results regarding key improved outcomes for PWE. While there was a focus on children in many of these studies, results should translate relatively well to the remainder of the epileptic population. Providing telemedicine options and accepting them as an alternative to specialist consultations would improve access to the healthcare system, increase medication adherence, and decrease costs for PWE (Fortini et al., 2020).

Existing step therapy legislation

Federal legislation

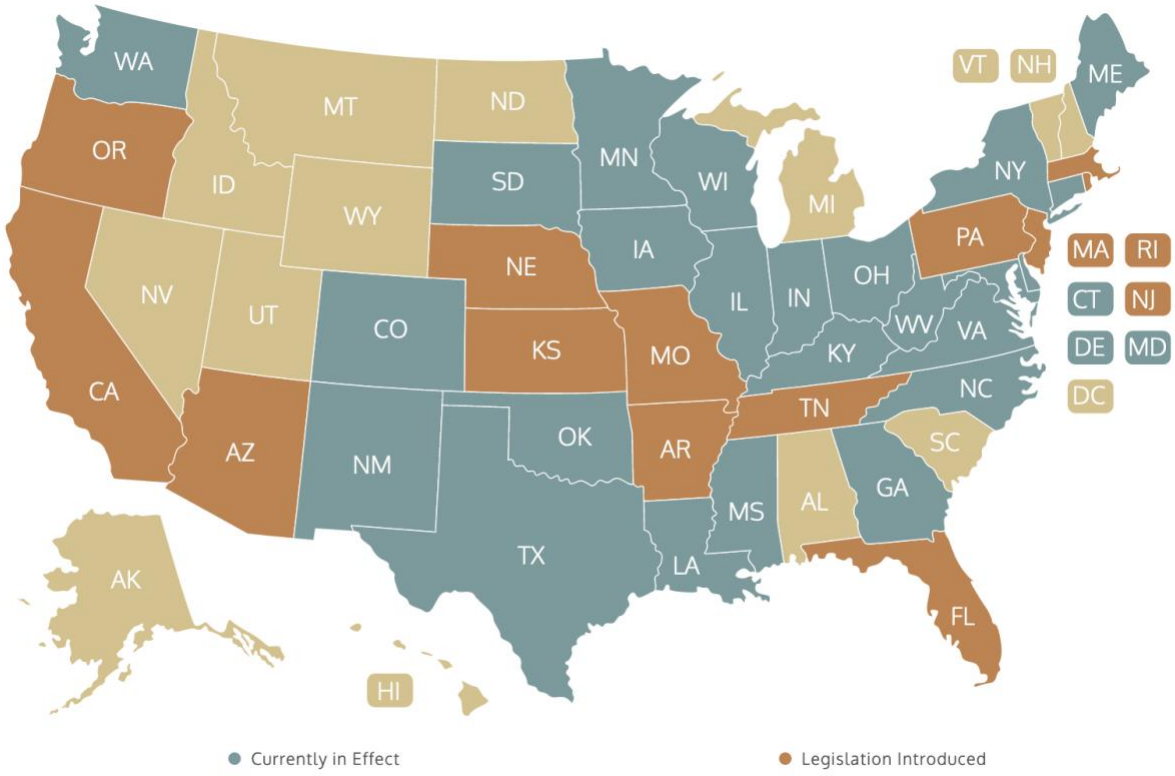
At the federal level, a bipartisan bill called the Safe Step Act was introduced in 2020 into the United States Senate to address step therapy practices by private insurance companies. This bill builds on some level of reform in twenty-five states (Givens, 2020). The bill does not prohibit any step therapy processes. Instead, the main goal of the bill is to generate transparency to prevent step therapy from being used inappropriately. Step therapy processes function by allowing patients in critical condition to be exempt from their requirements. The qualifications for being exempt differ by state. Private insurance companies can abuse step therapy by not granting exemptions for those who qualify. This process currently lacks transparency and oversight. The bill aims to increase transparency in order to get a gauge of the effectiveness of current step therapy processes, both regarding patient health and protecting insurance companies

from unnecessary costs. This bill would help generate information on step therapy, but does not address many of its problems.

State legislation

In Colorado, people are only exempt from step therapy if they are terminally ill or have gone through the steps of medication with a different provider ("Step Therapy Legislation By State," 2021). These exemptions were laid out in Colorado Senate Bill 17-203 and apply exclusively to private insurance companies. These protections are relatively intuitive and represent a common base level change to step therapy processes. In comparison to other states with legislation on step therapy, Colorado's exemptions are quite minimal.

Figure 2: Step therapy legislation by state



Source: National Psoriasis Foundation, 2021;
retrieved from https://www.steptherapy.com/step-therapy-legislation-by-state/

While national legislation did stall, twenty-five states have individually passed legislation addressing insurance-mandated step therapy, as seen in Figure 2. These mandates do not abolish step therapy practices, but rather provide important exemptions to mitigate the risks associated with step therapy requirements (Fink, 2019). The states with this type of legislation vary substantially regarding political party preferences. There doesn't seem to be a strong relationship between the party of the state congress and the likelihood that step therapy legislation is passed

("Step Therapy Legislation By State," 2021). Figure 2 does not mirror what a political map would look like, indicating that state legislatures with majorities from each party have passed legislation on step therapy. This would suggest that other factors, such as the desire of specific legislators and pressure from outside organizations, can heavily impact the introduction and legislation of step therapy regulations.

New York, among many other states, provides exemptions to step therapy in the event of contraindication. Drugs that are contraindicated likely have adverse effects on the patient's health ("Step Therapy Legislation By State," 2021). Another common exemption is for existing use. In many states, if a patient is currently stable on a prescription drug, they are exempt from the step therapy process ("Step Therapy Legislation By State," 2021).

Most states with legislation on step therapy include exemptions based on projected effectiveness. Intuitively, patients should not be forced to test a drug if it is not expected to be effective. Regulations indicate that effectiveness should be estimated based on health and other factors of the patient and clinical evidence on the drug ("Step Therapy Legislation By State," 2021). Especially when specialists with more expertise are involved, this facilitates the personalization of care by allowing doctors to more individually evaluate the patients.

A few states offer a more general exemption for drugs not in the patient's best interest. This exemption is hard to define effectively and certainly has overlap with other exemptions. Epilepsy has high rates of comorbidity, meaning that there are potentially additional risks for many patients. The exemption for drugs not in the patient's best interest is often based on if the drug increases the danger of a comorbid condition or decreases the patients ability to perform daily activities such as working and driving ("Step Therapy Legislation By State," 2021).

All of the state legislation on step therapy provides exemptions for patients to avoid steps in the process. However, these exemptions must still be processed and approved. Legislation provides guidelines for this process as well, often requiring response within 24-72 hours after the exemption is submitted for serious cases ("Step Therapy Legislation By State," 2021). Successful legislation should carefully regulate and guide the exemption process so that the goals of the exemptions are achieved. These efforts require transparency and sufficient oversight, but should avoid over-prescribing insurance companies on how to operate (Givens, 2020).

There is a notable lack of analysis on different exemptions to step therapy processes. Research validates that step therapy processes are slow to adapt to new developments in medication and create delays for effective care (Roebuck et al., 2015). Additionally, step therapy prompts reductions in medication use, resulting in some negative health outcomes. Unfortunately, the magnitude of the effects of step therapy practices has not been measured (Roebuck et al., 2015). Similarly, the effects of exemptions to step therapy processes have not been quantified. There

have been no intra- or inter-state analyses focusing on health outcomes as a result of step therapy. Subsequently, the effects must be estimated indirectly from experimental analysis. There is no academic consensus on best practices for regulation. Legislation in other states is the main precedent with which lawmakers must operate.

Criteria

The following criteria have been developed to represent the key factors for consideration for the Epilepsy Foundation of Colorado and the state government of Colorado. Alternatives will be evaluated upon three criteria to determine the most optimal path forward to combat issues faced by the epilepsy community of Colorado. Where possible, the criteria will be quantified; otherwise, criteria will be evaluated on a ranked basis.

Cost-effectiveness (60%)

Definition: This criterion measures the cost-effectiveness of each proposed alternative. Different alternatives have substantially different scopes. To be able to compare their impacts effectively, it is necessary to evaluate the cost-effectiveness of each. Cost-effectiveness is a measure of the impact per dollar a policy has.
Measurement: Projected cost will be measured in 2021 dollars. Effectiveness will be determined by estimating the decrease in the number of people with epilepsy that have seizures. The number of people reached by the alternative is evaluated to understand the impact of the alternative. Cost-effectiveness will be measured as a dollar cost per a one person decrease in people with epilepsy with seizures. See two formulas below for cost-effectiveness and the weighted score.

$$Cost - effectiveness = \frac{Total\ cost\ of\ the\ alternative}{(\%\ reduction\ in\ seizures) * (number\ of\ people\ reached)}$$

$$Cost - effectiveness\ weighted\ score = \left(\frac{Cost - effectiveness\ of\ highest\ rated\ alternative}{Cost - effectiveness\ of\ evaluated\ alternative} * 2\right) * 0.6$$

Political Feasibility (20%)

Definition: This criterion measures the anticipated difficulty of passing the potential alternatives. This criterion evaluates the degree to which the public and lawmakers will support potential policy ideas. Most potential interventions to address access to medication for those with epilepsy involve state government intervention. The policies of insurance companies and access to the healthcare system for PWE are most effectively impacted by governmental policy.

Measurement: Political feasibility will be mainly estimated by evaluating any similar legislation that has entered the Colorado state legislature. In cases where there are no similar pieces of legislation, other states who have had similar bills on the docket in recent history will be analyzed. Consistent with cost-effectiveness, each alternative will be scored on a scale from 0-2 (*low* = 0, *medium* = 1, *high* = 2). See below for the weighted scoring formula.

$$Political\ feasibility\ weighted\ score = \{0,1,2\} * 0.2$$

Administrative Feasibility (20%)

Definition: This criterion measures the anticipated difficulty of implementation for the proposed alternatives from an administrative aspect. A number of proposed alternatives will require the creation of a government program or substantial changes in policy within insurance companies. Alternatives with lower administrative feasibility are less likely to be implemented effectively.

Measurement: Administrative feasibility will be estimated by determining the scope of the proposed change and the level to which the current system and organization is prepared to implement it. Consistent with cost-effectiveness, each alternative will be scored on a scale from 0-2 (*low* = 0, *medium* = 1, *high* = 2). See below for the weighted scoring formula.

$$Political\ feasibility\ weighted\ score = \{0,1,2\} * 0.2$$

Evaluation of Alternatives

Alternative 1: Prohibit step therapy practices by private insurance companies

Step therapy protocols have been proven to delay effective care and be slow to respond to new developments in medication (Roebuck et al., 2015). The delays in effective care generate unnecessary risk and an increased chance of sudden unexpected death in epilepsy (SUDEP) (Givens, 2020). Prohibiting step therapy practices would prevent private insurance providers from using "fail first" strategies that require patients to try cheaper, less effective medication. This alternative would require that the Colorado state legislature mandate the removal of step therapy practices used by private insurance companies. Step therapy protocols not only require trials of certain medications, but also often necessitate specialist consultations. Prohibiting step therapy would subsequently remove these requirements as well. There could be an unintended secondary effect on the health outcomes of people with epilepsy (PWE) if they ultimately visit specialists less often.

Cost-effectiveness

Prohibiting step therapy practices increases some costs and decreases other for insurance companies. Newer generation medicine is more expensive and more effective. To find the expected cost of this alternative, I first inflated the average additional per person annual spending on anti-epileptic drugs from 2019 dollars to 2021 dollars (U.S. Bureau of Labor Statistics, 2021). Then, I multiplied that by the take-up rate and the number of people with epilepsy to determine the total additional cost of $110,547,300.

To find the cost savings, I multiplied the total number of PWE in Colorado by the take-up rate to find the number of people affected. I then multiplied that by the effectiveness rate of the intervention. That equals the number of people who will see cost savings, which I multiplied by the cost savings from attaining stable epilepsy in comparison to unstable epilepsy to find the total cost saved. Cost savings equal $88,749,400. I subtracted this value from the additional cost of medication to find the total estimated cost of $21,797,900.

To find cost-effectiveness, I divided the total cost by the number of people who no longer have seizures. The decrease in people who have seizures was found by multiplying the total number of PWE in Colorado by the percent that have seizures, the take-up rate, and the effectiveness rate. This generated a final cost-effectiveness estimate of **$4,283 per one person decrease in people with epilepsy with seizures.** The complete calculations can be found in Appendix A.

Political Feasibility

This policy alternative lacks precedent within Colorado and in other states. All previous legislation provides exemptions to step therapy ("Step Therapy Legislation By State," 2021). No

states have outlawed step therapy as a whole. Legislation on the national level is even more reserved, exclusively targeting the transparency of the process (Maas, 2019). This suggests that there is little appetite to adopt such an aggressive policy.

This alternative would also face strong opposition from insurance companies. Step therapy practices save money by preventing unnecessary expenditure. This alternative could cut heavily into their bottom lines. Due to these factors, I score this alternative as **low** on political feasibility.

Administrative Feasibility

This policy leaves little room for interpretation, making implementation rather straightforward. Insurance companies will simply scrap their step therapy processes. While this may change their pricing and how they accept customers in the long term, the short-term change is quite simple. Insurance companies have copay structures to split costs for medication with patients. They could charge a higher copay for more expensive medication in the future. This should be monitored to maintain the effectiveness of the proposed change. This could add an additional complexity down the road; monitoring the state of copays, specifically for PWE, will help mitigate this issue if it arises. High medication costs have been found as a cause of medication non-adherence in the past, which would greatly undermine the effectiveness of this proposal.

The same can be said about the government. The same enforcement mechanisms currently used to ensure exemptions to step therapy are being correctly applied can be utilized to ensure that companies remove their step therapy processes. As such, I score this alternative **high** on administrative feasibility.

Alternative 2: Add exemptions to step therapy practices for persons with epilepsy

Currently, Colorado has two exemptions to step therapy for PWE: being terminally ill and having completed the steps previously with another insurance provider. Exemptions allow patients to apply to skip steps in the step therapy practices of their insurance provider. Many other states have more comprehensive exemptions to step therapy protocols that have been mandated through state legislatures.

In this alternative, the Colorado state legislature would pass additional exemptions for contraindication and projected effectiveness. Contraindication is a separate condition that causes a treatment to have adverse health effects on a patient. Projected effectiveness uses expert medical opinions to evaluate the expected performance of certain medications based on the patient profile. Rather than forcing everyone to start on the same medication, providing an exemption for projected effectiveness would allow doctors to cater treatment better to their

patients. These exemptions already exist in certain states across the US ("Step Therapy Legislation By State," 2021).

Procedurally, doctors request exemptions for their patients. They evaluate the situation of their patient and communicate their patient's needs through the request for an exemption from the step therapy process. This is the standard process throughout the United States and streamlines the exemption request process to ensure that patients receive quick care. These exemptions must be processed and approved. Legislation should also include guidelines for this process as well, often requiring response within 24-72 hours after the exemption is submitted for serious cases ("Step Therapy Legislation By State," 2021).

This alternative focuses exclusively on step therapy within private insurance. There are some step therapy processes in Medicaid and Medicare. However, the regulation process for these programs is substantially different and requires different interventions. Some low-income Coloradans would likely be on Medicaid and remain subject to some step therapy protocols. This is worrying given that low-income people with epilepsy are more likely to have worse health outcomes in the first place. However, navigating the legislative and regulatory processes for public insurance is a separate and larger task. Actors at both the federal and state level of government have influence over how Medicaid and Medicare are implemented. Affecting policy for public insurance would necessitate an entirely separate intervention.

Cost-effectiveness

Adding exemptions to step therapy will both save and create costs for insurance companies and patients. There will be an increased use of newer generation medication that is more expensive. It is also more effective, leading to better health outcomes and lower hospital costs. In comparison to Alternative 1, the take-up rate of this alternative is lower. However, the effectiveness rate is higher given the additional vetting done in this alternative. The exemption request process ensures that the newer generation medication will be on average more effective for this group.

To find the expected cost of this alternative, I first inflated the average additional per person annual spending on anti-epileptic drugs from 2019 dollars to 2021 dollars (U.S. Bureau of Labor Statistics, 2021). Then, I multiplied that by the take-up rate and the number of people with epilepsy to determine the total additional cost of $27,636,800.

To find the cost savings, I multiplied the total number of PWE in Colorado by the take-up rate to find the number of people affected. I then multiplied that by the effectiveness rate of the intervention. That equaled the number of people who will see cost savings, which I multiplied by the cost savings from attaining stable epilepsy in comparison to unstable epilepsy to find the total

cost saved. This equaled $24,960,800. I subtracted this value from the additional cost of medication to find the total estimated cost of $2,676,000.

To find cost-effectiveness, I divided the total cost by the number of people who no longer have seizures. The decrease in people who have seizures was found by multiplying the total number of PWE in Colorado by the percent that have seizures, the take-up rate, and the effectiveness rate. This generated a final cost-effectiveness estimate of **$1870 per one person decrease in people with epilepsy with seizures.** The complete calculations can be found in Appendix A.

Political Feasibility

Colorado's existing exemptions are quite small in comparison to many other states. Twenty-four states other than Colorado have step therapy legislation currently in effect. Many of these states have substantially more comprehensive exemptions than Colorado ("Step Therapy Legislation By State," 2021). This issue does not seem to be heavily partisan; both Texas and New York, among many other states across the political spectrum, have legislation currently in effect on step therapy.

This alternative has strong precedence both in Colorado and in other states. The Colorado legislature has previously passed some level of exemptions. Other states also provide a precedent for the specific exemptions being proposed in this alternative. However, we can expect opposition from insurance companies. While this alternative itself may not present a big risk to their bottom lines, it sets a precedent for further exemptions and changes for all diseases, not just epilepsy. Insurance companies may choose to fight this in hopes of avoiding a cascade of further legislation that could substantially decrease their profits. Precedent makes this alternative quite politically feasible, with pushback projected to come from insurance companies. I score this alternative **medium** on political feasibility.

Administrative Feasibility

This alternative would add extra work for insurance companies. Any requests for exemptions require evaluation and decisions on in a timely manner, generally between 24-72 hours ("Step Therapy Legislation By State," 2021). Private insurance companies in Colorado already have built out infrastructures to process exemptions due to the limited exemptions that already exist in the state. This policy would require an expansion of insurance companies' infrastructures to deal with a higher volume of requests, as well as additional training and guidelines on how to process the new types of requests. While the volume of requests by PWE will significantly increase, this likely does not equate to an overwhelming increase in total requests for exemptions considering the volume of requests from people with other diseases and conditions. Since private insurance companies already have some infrastructure to process exemption requests, I score this alternative **medium** on administrative feasibility.

Alternative 3: Fund telemedicine programs for specialist consultations

Specialist consultations are heavily intertwined in treatment for PWE due to both requirements and necessity. Step therapy practices often include a specialist consultation as a requirement. Additionally, specialist requirements have been proven to increase the health outcomes for people with epilepsy. Despite the apparent need for specialists, access to specialists is limited for much of the population, with one third of PWE not seeing a specialist in the last year (CDC, 2020). There is not an abundant supply of specialists in rural areas, making it extremely difficult for those populations to fulfill requirements and receive care (Liverman et al., 2012).

This alternative would create a state-run program that would fund the creation of a telemedicine network of epilepsy specialists. The government would set up the portal and network, as well as coordinate the number of specialists to fit demand. Specialists would receive payments from insurance companies and individuals for their services, with additional payments for the services provided by the government. In the future, this program could be reevaluated on its effectiveness. If these telemedicine consultations are not being accepted by insurance companies, the government may have to take legislative action that ensures telemedicine specialist visits meet step therapy requirements.

Studies on telemedicine offer encouraging results regarding key improved outcomes for PWE. Providing telemedicine options and accepting them as an alternative to in-person specialist consultations would improve access to the healthcare system, increase access to medication, and decrease costs for PWE (Fortini et al., 2020). This bridges the access gap for the rural population. Additionally, there could be optimism for this having lower costs than an in-person specialist visit, creating more accessibility for low-income populations.

Cost-effectiveness

To find the total cost, I estimate the number of PWE that will use these services by multiplying the total number of PWE in Colorado by the telemedicine usage rate (Singh & Marquardt, 2020). I then multiply this by the annual number of visits per person to find the total number of visits. Finally, I multiply the total number of visits by the cost per visit to estimate the total cost as $13,278,400 (Zocchi et al., 2020).

To find the cost-effectiveness, I divide the total estimated cost by the number of people that no longer have seizures. The number of people that would no longer have seizures was calculated by multiplying the number of people using the service by the reduction in seizures from regular specialist consultations (Lowerison et al., 2019). This generated a final cost-effectiveness estimate of **$2,314 per one person decrease in people with epilepsy with seizures.** The complete calculations can be found in Appendix A.

Political Feasibility

Colorado's annual budget for FY 2020-2021 allocates $12.033 billion for Health Care Policy and Financing (Colorado Legislative Council, 2021). The annual cost of this policy alternative is miniscule compared to the total spending on healthcare. This makes the policy more feasible given that it is not an extremely large financial commitment. Additionally, this would be a good trial for expanding telemedicine further, which is being considered in numerous states. In part due to the impact of COVID, about 300 bills have been introduced nationwide to expand access to telemedicine (Jercich, 2021) This indicates that this topic is not only on the agenda, but also has relative support. Nevertheless, this policy alternative would require spending and desire from the Colorado state legislature. Based on these factors, I score this alternative **medium** on political feasibility.

Administrative Feasibility

This policy alternative would require the government to delegate the creation and management of this service to the bureaucracy. The state would have to decide whether to contract this out or to do it themselves. Contracting is a good option, as some infrastructure should already exist from similar programs. To maintain the effectiveness of this alternative, the state would need to be very considerate of the quality of the company they contract this out to. Contracting out this program would impose a lower burden on the state, but it would still need to monitor the effectiveness of the program and contractor. Even with contracting, this alternative would require the state to manage the creation of a telemedicine center. Subsequently, I score this alternative **medium** on administrative feasibility.

Outcomes Matrix

	Cost-Effectiveness	Political Feasibility	Administrative Feasibility	Cumulative Score
1 – Prohibit step therapy	**$4,283 per 1 person decrease in people with epilepsy with seizures** ($1,870/$4,283) x 2 = .87 .87 x .60 = .52	**Low** 0 x .20 = 0	**High** 2 x .20 = .4	.52+0+.4 = **0.92**
2 – Add exemptions to step therapy	**$1,870 per 1 person decrease in people with epilepsy with seizures** ($1,870/$1,870) x 2 = 2 2 x .60 = 1.2	**Medium** 1 x .20 = .2	**Medium** 1 x .20 = .2	1.2+.2 +.2= **1.60**
3 – Fund telemedicine programs	**$2,315 per 1 person decrease in people with epilepsy with seizures.** ($1,870/$2,315) x 2 = 1.61 1.61 x .60 = .97	**Medium** 1 x .20 = .2	**Medium** 1 x .20 = .2	.97+.2+.2= **1.37**

Recommendation

Based on these calculations, I recommend **Option 2: Add exemptions to step therapy practices for people with epilepsy**. This alternative scores highest on cost-effectiveness, the criterion most heavily weighted. Adding exemptions to step therapy is tied for being the most political feasible. Since every alternative would need to go through the Colorado state legislature, it is critical that it can feasibly be passed. It does score lower on administrative feasibility, as it forces insurance companies to integrate a large volume of new exemptions into their exemption approval process. The difficulty that will come along with implementation does not take away from the large benefits of this alternative. The effects of this policy's implementation challenges can be lessened by effective planning and careful oversight.

By best targeting people who will be positively affected by the changes, this alternative achieves good cost-effectiveness and is less likely to face opposition in Colorado's state congress. This policy addresses the problem without imposing too many additional costs on patients and insurance providers. On aggregate, PWE should see substantially better health outcomes on aggregate from the additional exemptions to step therapy. This realistic alternative should be a priority for the Epilepsy Foundation of Colorado.

Implementation

I recommend the Colorado state legislature add exemptions to step therapy practices for people with epilepsy. These exemptions would allow some people with epilepsy (PWE) to access newer generation, more expensive medication without completing previous steps, which include failing other medications. The additional exemptions allow PWE to skip steps based on the projected effectiveness of a medication according to their doctor. This option is the most cost effective among those evaluated, but has some challenges when it comes to feasibility. Careful and intentional implementation strategies can ease these concerns.

This change would require new legislation in the Colorado state legislature. Other states that have passed similar legislation have already gone through this process. Specifically, New York passed legislation in 2016 adding exemptions across step therapy based on projected effectiveness (*New York S03419 | 2015-2016 | General Assembly*, 2016). The bill included a few other provisions and was not specific to just epilepsy; nevertheless, it provides the best precedent.

Windows of opportunity are key to building momentum on a cause. Windows of opportunity come from problem and political streams (J. Kingdon, 1995). Large events such as natural disasters fall under the problem stream. While focusing events are often very effective at catalyzing change, there does not appear to be a focusing event relevant to epilepsy or step therapy coming anytime soon. There are not really large enough events to sway public opinion or legislative agenda on a niche topic such as this. The political stream opens up windows of opportunity through administration changes, ideological shifts in state congress or committees, and public opinion changes (J. Kingdon, 1995). For step therapy and epilepsy, the political stream is the only realistic possibility that a window of opportunity opens. In the 2020 elections, Democrats extended their majority in the Colorado State Senate (*Colorado State Senate*, 2020). While step therapy legislation is not an extremely partisan issue, Democrats may be more willing to support legislation on healthcare in general.

The first step of introducing a bill to legislature is obtaining sponsors for the bill. Providing a base draft to a representative and their office is an effective way to make the process of sponsorship easier for them (J. Kingdon, 1995). As an organization, your main priority should be drafting a quality base for legislation and enlisting support from members of the Colorado state congress. The bill in New York was sponsored by 11 Democrats and 7 Republicans (*New York S03419 | 2015-2016 | General Assembly*, 2016). These exemptions do not need to become partisan. Securing sponsors from both parties will help prevent discussion from turning partisan.

Bills must be introduced in advance of the legislative session. Colorado requires bills be submitted by December 1st (*The Legislative Process | Colorado General Assembly*, 2021). In

order to get this bill on the docket for the next legislative session, the bill must be drafted, and sponsors must be confirmed by then. As such, this process must be completed in a few months. Once a bill is introduced, it is referred to a committee. This would be the House Committee of Health and Insurance, which is similar to the committee the New York legislation went to (*New York S03419 | 2015-2016 | General Assembly*, 2016). Gaining support from these members is critical to getting the bill to the floor. Approaching these members before the bill is in committee would be more effective than waiting. Asking one of the ranking members to sponsor the bill may be the most effective means of ensuring the bill reaches the Colorado House floor. Susan Lontine is the committee chair and has been the prime sponsor on a number of bills that protect and improve care for healthcare patients (*Susan Lontine | Colorado General Assembly*, 2021). Lontine is a key stakeholder to approach for advice and support given her position and past actions.

After going through both houses, the bill would be referred to Governor Jared Polis. Polis made healthcare his main priority after being elected governor in 2018 (Fulcher, 2020). Polis has stated that he believes Coloradans are being ripped off in the healthcare system, receiving poor care for high costs (Fulcher, 2020). Adding exemptions to step therapy would protect PWE, which is in line with Polis's goals. This suggests that Polis signing the bill into law will not be an obstacle.

The pathway through the Colorado legislative process does not immediately present obstacles within the process. A major concern would be opposition from insurance companies. This change would increase costs for these companies. While the increased costs seem worth the improved care for PWE, insurance companies across the nation have been increasingly integrating step protocol processes into their overall structures (Cohen, 2019). Insurance providers have found these to effectively cut costs and subsequently oppose restrictions on step therapy.

Limiting opposition from insurance companies will help make this process move more smoothly. This starts during legislation drafting. Meeting with representatives from insurance companies to discuss the proposed changes could help make the bill more acceptable. For example, soliciting suggestions from these companies on how they would define projected effectiveness and at what point that qualifies as an exemption would avoid potential opposition or amendments later in the legislative process. This meeting would also serve to ensure that any new exemptions would fit into the existing infrastructure of the insurance companies for exemption processing. While the insurance companies would likely still oppose the legislation as a whole, the bill itself will be less intrusive on their processes and business. Finally, providing key cost estimates will also help limit opposition. Insurance companies may envision extreme increases in annual costs due to these changes. Providing reasonable estimates for the cost increases can help avoid insurance companies from catastrophizing about the changes and responding with strong opposition.

Upon passing this legislation, there are still steps that can be taken to maximize the success of this program by addressing roadblocks that arise. Unexpected problems may arise with these exemptions. Checking in with insurance companies and patients annually after implementation to evaluate the success of the policy will allow potential problems to be voiced. A public hearing through the insurance commissioner on this topic would provide a space for this conversation to occur. Major problems that arise could be brought back into the policy sphere to adjust laws, rules, and regulations in order to maximize the benefits of the policy.

Conclusion

This report has emphasized the problems facing the epileptic community of Colorado. Too many Colorado residents with epilepsy struggle to receive effective care, generally due to issues of access and step therapy practices. As health care costs continue to rise both in Colorado and across the United States, this problem will likely get worse. Adding additional exemptions based on projected effectiveness in line with precedent from other states provides an opportunity to improve the health outcomes of tens of thousands of Coloradans. This recommended alternative proves to be quite cost-effective and is feasible enough administratively and politically to be a realistic option going forward. The Epilepsy Foundation of Colorado should focus on educating state lawmakers and providing them with the resources to pass legislation that improves the healthcare landscape for people with epilepsy in Colorado.

Appendix A: Cost-effectiveness calculations

General adaptations and figures

Adjusting for inflation

- To change 2019 dollars to 2021 dollars, multiply 2019 dollars by 1.039 (U.S. Bureau of Labor Statistics, 2021)

Number of people with epilepsy in Colorado

- 56,800 (CDC, 2020)

Per person cost savings for stable epilepsy adjusted for inflation:

- $9399 * 1.039 = $9765 (AJMC, 2020)

Alternative 1: Prohibit step therapy practices by private insurance companies

Cost calculations

Additional Costs

1. Additional per person AED cost adjusted for inflation:
   *(AED * Drug cost multiplier * inflation factor) =*
   $3122 * 1.5 *1.039= $4685
   (AJMC, 2020)(Holland & Jewell, 2020).
2. Total number of PWE adjusting for take-up rate:
   *(PWE in Colorado * take-up rate) =*
   56,800 * 0.4 = 22720
   (Givens, 2020, p. 2)
3. Total additional cost from newer generation medication:
   $4865 * 22720 = $110,547,300

Cost Savings

1. Total number of PWE adjusting for take-up rate:
   22720 (see above)
2. Determine the number of people who see cost savings due to better treatment:
   *(Number of people treated * cost savings rate) =*
   22720 * 0.4 = 9088
   (Faught et al., 2015)
3. Total cost savings:
   *(per person savings * number of people affected) =*
   $9765 * 9088 = $88,749,400

Net Cost

1. Cost savings subtracted from the additional costs:
   $110,547,300 - $88,749,400 = $21,797,900

Effectiveness calculation

1. Number of PWE who have seizures:

*(PWE in Colorado * % with seizures) =*
56800 * 0.56 = 31808
(Tian, 2018)

2. Determine how many people are effectively treated:
*(PWE with seizures * take-up rate * effectiveness rate of treatment) =*
31808 * 0.4 * 0.4 = 5089.28
(Givens, 2020)(Faught et al., 2015)

Cost-effectiveness calculation

$$Cost - effectiveness = \frac{\$21{,}797{,}900}{5089.28} =$$

$4,283 per 1 person decrease in people with epilepsy with seizures

Alternative 2: Add exemptions to step therapy practices for persons with epilepsy

Cost calculations

Additional Costs

1. Additional per person AED cost adjusted for inflation:
*(AED * Drug cost multiplier * inflation factor) =*
$3122 * 1.5 *1.039= $4685
(AJMC, 2020)(Holland & Jewell, 2020).
2. Total number of PWE adjusting for take-up rate:
*(PWE in Colorado * take-up rate) =*
56,800 * 0.1 = 5680
(Givens, 2020, p. 2)
3. Total additional cost from newer generation medication:
$4865 * 5680 = $27,636,800

Cost Savings

1. Total number of PWE adjusting for take-up rate:
5680 (see alternative 2 additional costs # 2)
2. Find the number of people who see cost savings due to better treatment:
*(Number of people treated * cost savings rate) =*
5680 * 0.45 = 2566
(Faught et al., 2015)
3. Total cost savings:
*(per person savings * number of people affected) =*
$9765 * 2566 = $24,960,800

Net Cost

1. Cost savings subtracted from the additional costs:
$27,636,800 - $24,960,800 = $2,676,000

Effectiveness calculation

1. Number of PWE who have seizures:
   31808 (see alternative 1 effectiveness calculation #1)
2. Determine how many people are effectively treated:
   *(PWE with seizures * take-up rate * effectiveness rate of treatment) =*
   31808 * 0.1 * 0.45 = 1431.36
   (Givens, 2020)(Faught et al., 2015)

Cost-effectiveness calculation

$$Cost - effectiveness = \frac{\$2{,}676{,}000}{1431.36} =$$

$1870 per 1 person decrease in people with epilepsy with seizures

Alternative 3: Fund telemedicine programs for specialist consultations

Cost calculations

1. Number of people that will use telemedicine:
   *(PWE in Colorado * take-up rate) =*
   56,800 * 0.25 = 14200
   (Singh & Marquardt, 2020)
2. Total visits:
   *(People who use telemedicine * number of visits per person) =*
   14200 * 3 = 42600
3. Total Cost:
   *(Number of visits * cost per visit * inflation factor) =*
   42600 * $300/visit * 1.039 = $13,278,400
   (Zocchi et al., 2020)

Effectiveness calculation

1. Number of people that will use telemedicine:
   14200 (see alternative 3 cost calculations #1 above)
2. Estimate of seizures reduced:
   *(PWE reached * effectiveness rate of treatment) =*
   14200 * 0.404 = 5736.8
   (Lowerison et al., 2019)

Cost-effectiveness calculation

$$Cost - effectiveness = \frac{\$13{,}278{,}400}{5736.8} =$$

$2314 per 1 person decrease in people with epilepsy with seizures

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