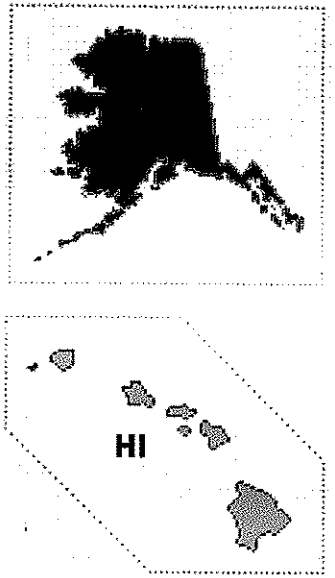
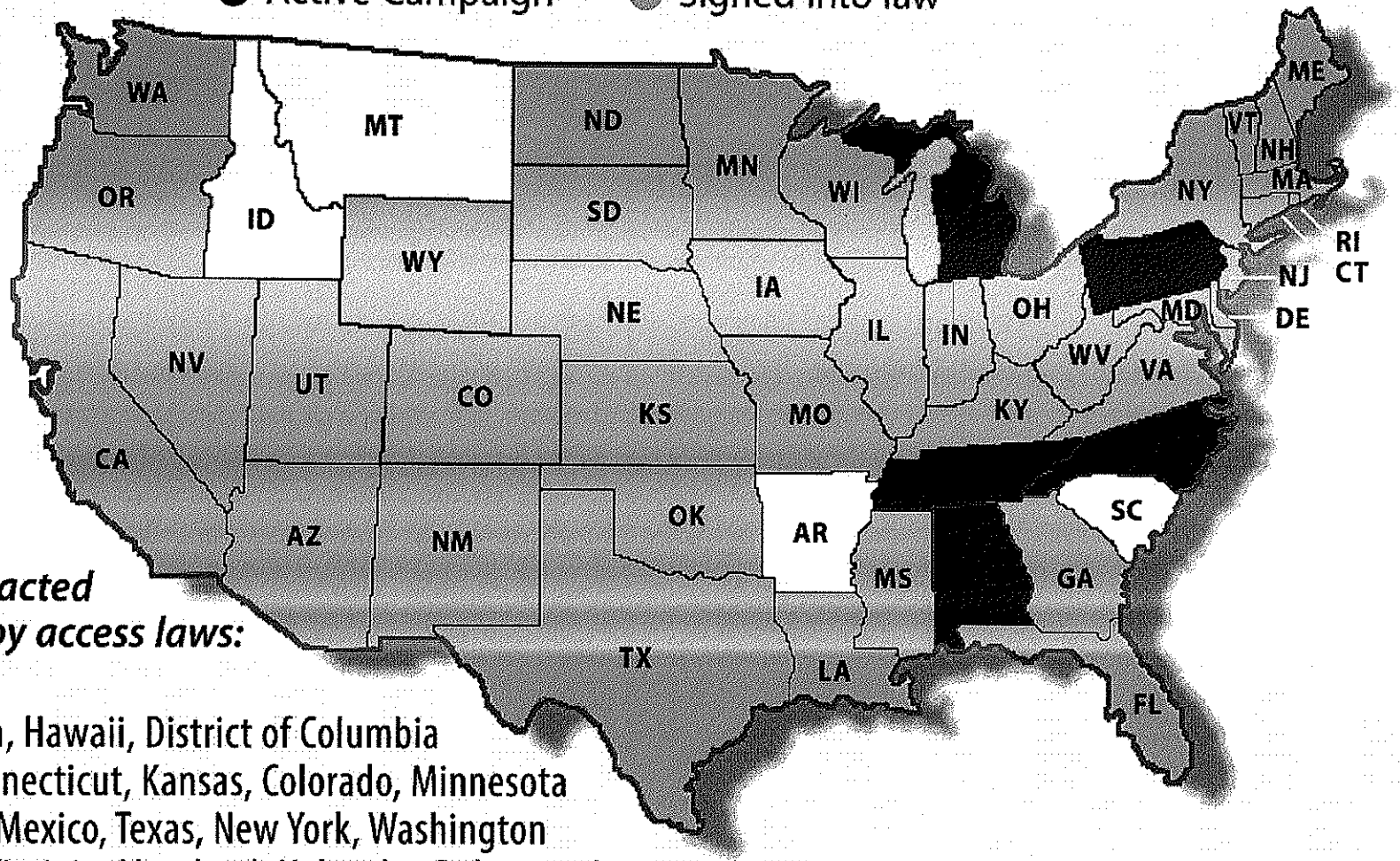
International Myeloma Foundation

SPEAC
STATE PATIENTS EQUAL ACCESS COALITION

Oral Chemotherapy Access Legislative Landscape – October 2015

● Active Campaign ● Signed into law





40 states have enacted oral chemotherapy access laws:

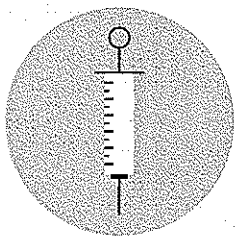
2008 Oregon
2009 Indiana, Iowa, Hawaii, District of Columbia
2010 Vermont, Connecticut, Kansas, Colorado, Minnesota
2011 Illinois, New Mexico, Texas, New York, Washington
2012 New Jersey, Virginia, Maryland, Nebraska, Delaware, Louisiana
2013 Massachusetts, Oklahoma, Utah, Nevada, Florida, Rhode Island, California
2014 Maine, Missouri, Wisconsin, Kentucky, Georgia, Arizona, Ohio
2015 Wyoming, South Dakota, West Virginia, Mississippi, North Dakota, New Hampshire

ORAL ONCOLOGY PARITY LAWS

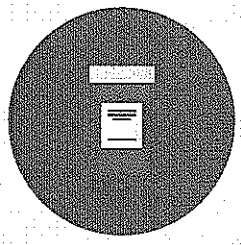
The way we treat cancer is changing—with oral anti-cancer medications playing an increasingly important role. These therapies—available in pill form—directly attack cancer cells, often with fewer side effects.

Oral oncology parity laws can assist patients in accessing these new innovative therapies. As of May 2015, 39 states and the District of Columbia have passed these laws. Is your state one of them?

WHAT IS ORAL ONCOLOGY PARITY?



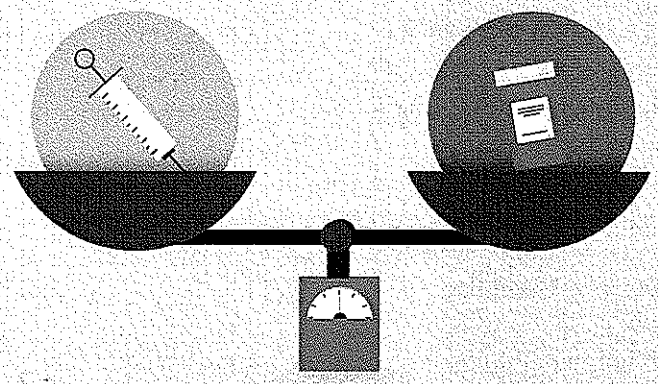
Traditional anti-cancer medications are primarily administered intravenously and covered under a health plan's medical benefit, often requiring patients to pay a minimal co-pay or no cost at all for the medication.



Oral anti-cancer medications are usually part of the health plan's pharmacy benefit, often resulting in high, burdensome out-of-pocket costs through coinsurance (requiring patients to pay a percentage of the overall cost of the prescription therapy).

This disparity negatively impacts patient adherence[1] and forces physicians to make decisions based on outdated health plan benefit designs rather than what is best for the patient.[2]

WHAT DO ORAL ONCOLOGY PARITY LAWS DO?



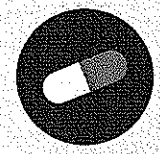
Oral oncology parity laws are intended to address this problem of inequitable coverage between oral and IV anti-cancer medications by requiring health plans to equalize a patient's out-of-pocket costs between oral and IV therapies.

The laws do not mandate coverage of oral chemotherapy, but simply state that if a health plan covers "chemotherapy" treatment, the patients' out-of-pocket costs must be the same, regardless of how the therapy is administered.

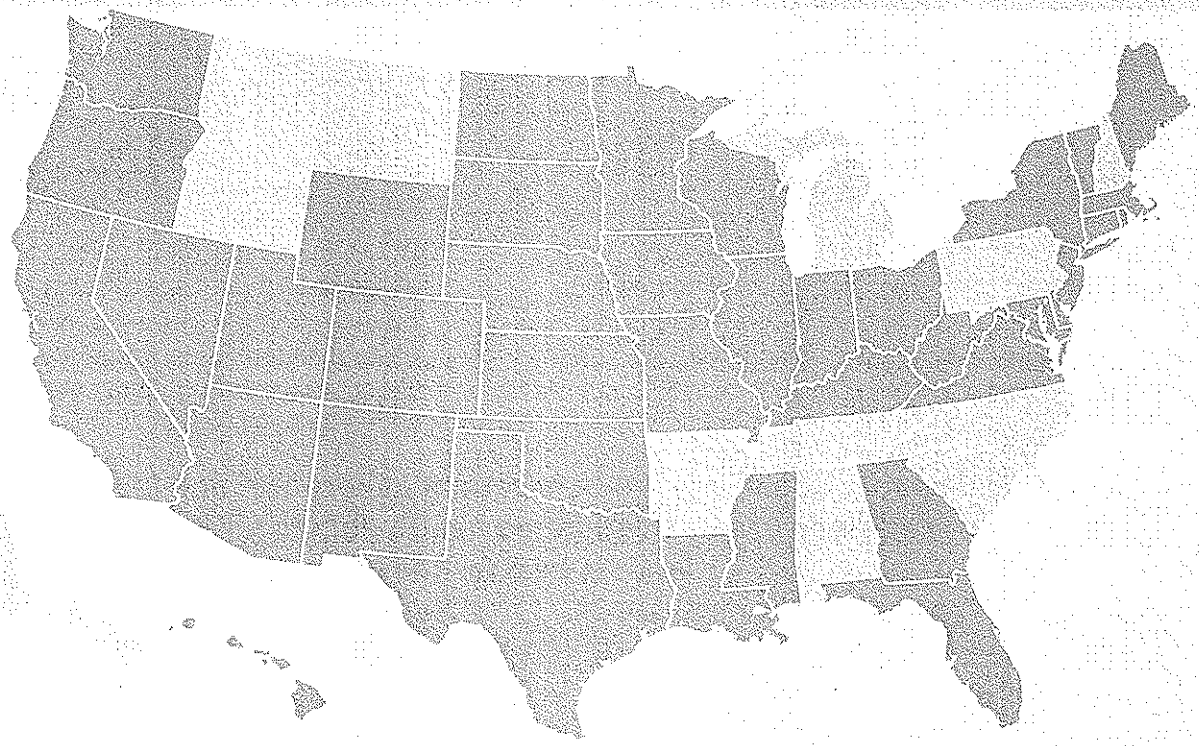
WHO BENEFITS FROM THESE LAWS?

As of May 2015, 39 states and the District of Columbia (DC) have passed legislation to limit patient out-of-pocket costs for oral anti-cancer medications and a number of others are expected to take action in 2015. However, state laws can only impact certain health plans and do not apply to Medicare or Medicaid. Health plans covered under the federal Employee Retirement Income Security Act (ERISA) (usually large, multi-state health plans) are also exempt. **Since state laws can only protect a portion of cancer patients, a federal bill like the "Cancer Drug Coverage Parity Act" is important to fill the gaps.**

Oral oncology parity laws allow many patients and physicians to choose the right therapy that offers the most hope---without worrying about outdated health plan benefit designs that charge patients more simply because the therapy they need is only available in pill form.



It is estimated that 25-35% of the therapies in the oncology pipeline will only be available in pill form.[3] These laws ensure that patients fighting cancer today—and those who will be diagnosed in the future—have access to the innovative therapies offering them the best chance at survival.



An increasing number of state legislatures have taken steps to ensure patients have equal access to oral anti-cancer therapies. **In addition to the 39 states and the District of Columbia that have passed oral oncology parity laws, there is a federal bill, the "Cancer Drug Coverage Parity Act," that has been introduced in Congress.**

Where can I go for more information or to learn about the law in my state?

Visit the State Patients Equal Access Coalition website at **www.speac.myeloma.org** for more information on the important role Oral Oncology Parity laws play and to download state-specific fact sheets on all the existing state laws. For more information on efforts to pass a federal bill ensuring oral oncology parity, please visit **www.peac.myeloma.org**.

[1] Streeter, SB, Schwartzberg, L. and Johnsrud, M. "Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions." Journal of Oncology Practice, 7.3S 46s-51s.

[2] Neumann, PJ et al. "Cancer Therapy Costs Influence Treatment: A National Survey of Oncologists." Health Affairs, 29, no. 1 (2010):196-202.

[3] Geynisman, DM and Wickersham, KE. "Adherence to Targeted Oral Anticancer Medications." Discovery Medicine, 2014; 17, no. 095

MYTH v. FACT: Setting the Record Straight in Michigan about Senate Bill 625 (Fair Access to Oral Oncology Medications)

As of November 2015, 40 states and the District of Columbia have passed legislation to lower the monthly costs for those taking oral anticancer medications. For countless cancer patients, this means thousands of dollars saved each month and increased access to the most effective therapies. However, Michigan's health plans are working hard to prevent SB 625 from moving forward in the Michigan legislature for the third consecutive legislative session, claiming it will increase premiums for all policyholders, impact few patients, among other unsubstantiated claims.

Myth: SB 625 will increase premiums for all policyholders in Michigan.
Fact 1: Based on a study by Milliman, an independent actuarial consulting firm, state laws to limit patient out-of-pocket for oral anticancer therapies will only minimally increase health insurance premiums if they increase premiums at all. Specifically, the study revealed an average nominal increase of only $0.50 per member per month for most plans. This translates to a mere 0.17% rise in premiums (a typical plan in this context costs over $300 per member per month).

Fact 2: Fiscal impact studies conducted in states like Kentucky, Indiana, Missouri and a host of others where legislation has passed, showed similar results---little to no impact on health insurance premiums.

Myth: SB 625 is a mandate.
Fact 1: SB 625 does not force health plans in Michigan to cover a service or any new benefit currently not required by state insurance law. Michigan's health plans cover oral anticancer medications for patients, so the issue is not about coverage, but an inequity in out-of-pocket costs to patients whose oncologist has determined that chemotherapies that come in pill form are the most effective to treatment to fight their cancer vs. those receiving IV therapies.

Fact 2: CMS has clearly stated in a FAQ document that an oral oncology parity law is a cost-sharing requirement, not a coverage benefit, and states are not required to defray the cost of oral parity laws.

Myth: Patients can choose between oral and IV forms of chemotherapy treatment.
Fact 1: SB 625 is not about choice and convenience to the patient, but what is medically necessary and in the best interest of the patient. Nearly all of the oral anticancer medications currently in use **do not** have an IV or generic equivalent and are specifically indicated as the first and most effective treatment for a range of cancers, making affordability to the patient even more urgent.

Fact 2: New oral therapies that are coming to market have different mechanisms of action than older IV medications. As these therapies become the new standard of care, it is important that patients can access these medications. Of the approximately 1,000 cancer medications in the pipeline, approximately 80% are first in class medications that take a novel approach to treating a specific type of cancer.

Myth: New oral anticancer medications are much more expensive than intravenous (IV) medications.
Fact 1: Treating cancer, regardless of how the treatment is administered, is an expensive prospect. However, in many cases, oral anticancer medications are more cost effective than intravenous (IV) therapies. For example, the cost of Tarceva, an oral anticancer medication used to treat lung cancer, is estimated at $20,042 as compared to $20,630 for the IV alternative. For metastatic breast cancer patients the cost of the oral oncology treatment is $35,842 annually compared to $43,353 for IV therapy.

Fact 2: For some cancers, the oral anticancer medication is the standard of care and only treatment available for the cancer those patients.

Fact 3: There are additional administrative costs associated with IV medications that can add thousands of dollars each month to the cost of treatment.

Fact 4: Patients taking oral chemotherapies are not doing so out of convenience, but because it is the most effective therapy to treat their cancer.

Fact 5: Patients can often undergo what is known as "combination therapy" where IV/injected and oral anticancer drugs are used to treat their cancer, making affordable access to both imperative.

Myth: SB 625 applies to a very limited number of insurance plans in Michigan, impacting only 0.09% or 9,000 patients.
Fact 1: While it is true that **SB 625** will not impact certain health plans exempted by the federal Employee Retirement Income Security Act (ERISA), this bill would still apply to as much as 35% of the market in Michigan. To address this disparity, oral oncology parity legislation has been introduced at the federal level, and until Congress takes action, states are working to protect as many cancer patients as possible.

Fact 2: The 9,000 lives that would benefit from the passage of an oral oncology parity law cited by Michigan's largest health plan only reflects new cases of cancer in one year and does not capture those currently living with the disease and still in treatment, who could benefit from passage of the bill as well.

Fact 3: 9,000+ lives may be insignificant to health plans and some lawmakers in Michigan, but passage of this bill often means the difference between life and death for cancer patients.

Myth: The recent trend in consolidation of private oncology practices and community health centers, merging with hospitals in Michigan, is a consequence of the high costs of oral oncology medications.
Fact: Consolidation in Michigan of private practices and community health centers, with larger facilities, like hospitals, is unrelated to oral oncology parity legislation; instead, the bill seeks to address the faulty benefit design of a patient's health insurance plan that has not kept up with innovations in cancer treatment and therefore discriminates against the type of cancer a patient may be diagnosed with by putting their treatment option out-of-reach.

Myth: SB 625 is not necessary in Michigan, as drug manufacturers and charitable organizations have patient-assistance programs to help them get the medications they need.
Fact: While most pharmaceutical companies do offer some type of financial assistance to those in need, it is only available to a limited number of patients with strict eligibility requirements, and programs administered by charitable organizations are even smaller. Patients typically need to reapply to these programs every year, creating instability and uncertainty around how they will get access to their medications. This leaves an untold numbers of patients without a safety net if faced with astronomical out-of-pockets for their oral therapies.

Myth: The Affordable Care Act solves this problem.
Fact: While the Affordable Care Act put in place annual out-of-pocket maximums for patients, unfortunately this does not help patients who have cancer that may be required to pay thousands of dollars in coinsurance per prescription each month until they reach their out-of-pocket maximum. In fact, since the passage of the Affordable Care Act, the number of plans charging high coinsurances for specialty drugs has increased dramatically. For example, in 2015, approximately 41% of Silver Plans had coinsurance greater than 30% on specialty tier drugs.

FINAL FACT: Oral Oncology Drugs Are the Wave of the Future in Cancer Care
Between 25%-30% of new anticancer treatments in the research pipeline will only be available in pill form, making oral therapies an increasingly important component of cancer treatment for a host of cancers. With the advances in cancer treatment over the last decade, many of these innovative therapies are already the standard of care and for some cancers the only treatment that works.

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Mandates on States & Premium Increases for All?

A Snapshot of Impact of Providing Cancer Patients Affordable Access to Oral Anticancer Treatments

STATE	YEAR PARITY LAW ENACTED OR PENDING LEGISLATION	REVIEWED AS MANDATE & FOR FISCAL IMPACT BY POLICYMAKERS	OUTCOME OF REVIEW
California	January 1, 2015	Analysis conducted by California Health Benefits Review Program.	Analysis found a negligible increase in premiums of .00144%.
Colorado	January 1, 2011	An official study was not conducted by the Division of Insurance (DOI), but DOI did respond to an inquiry from a Tennessee legislator, regarding premium increases since enactment of parity law.	In response to the TN legislator, CO Comm. of Insurance stated, "Because of the extent of changes to state and federal law, affecting health insurance premiums and cost sharing, we cannot attribute any change due to this specific provision."
Connecticut	January 1, 2011	Official study not conducted by the CT Insurance Department, but department did respond to an inquiry from a TN legislator, regarding premium increases since enactment of parity law.	In response to the TN legislator, CT Insurance Department Counsel, N. Beth Cook states, "while [health] plans raised concerns during the legislative process, once the law was enacted, we have not had concerns raised.
Illinois	January 1, 2012	An official study was not conducted by the Illinois Department of Insurance, but the department did respond to an inquiry from a Tennessee legislator, regarding premium increases since enactment of parity law.	**Q:** "Have any health plans raised specific concerns about the oral chemotherapy parity requirement and/or claimed that the new requirement has resulted in an increase in health insurance premiums?" **A:** "Yes; but that has been a standard defense against any new mandates. To date, such claims have not been supported by actual rate increases."

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Indiana	January 1, 2010	Yes. Bill sponsor sent letter to Indiana Insurance Department, asking if premiums had increased, as a result of enactment of oral chemotherapy parity law.	Indiana Department of Insurance confirmed one year after enactment that "no increase [in premiums] has materialized at this time."
Kansas	April 1, 2010	The Kansas State Employees Health Care Commission conducted a review of impact on premiums.	KS State Employees Health Care Commission found "minimal impact to the health plan finances."
Kentucky	January 1, 2015	Yes. Study conducted by the Kentucky Department of Insurance.	Determined an increase in all premiums between 67-84 cents per month per member.
Maine	January 1, 2015	Yes. Study conducted by the Maine Department of Insurance.	Determined no increase in premiums.
Massachusetts	May 1, 2013	Mandated Benefit Review of SB 1070 (An Act to Relative to Oral Cancer Therapy) conducted by the Division of Health Care Policy and Finance.	Found that bill would cause no more than a 0.044 percent increase in insurance premiums. The five-year total estimated impact on premiums ranges from 0.008 to 0.044 percent of annual premium."
Missouri	January 1, 2015	Report commissioned by Missouri Joint Committee on Legislative Research- Oversight Division.	Report estimated a 0.23%, or $0.81, per member increase.
Oregon	January 1, 2008	Yes, the Oregon Insurance Division (OID) conducted a review.	OID stated impact on premiums "very MINIMAL." Just 9 out of 79 plans cited a minimal impact on premium rates.
Texas	September 1, 2011 **(The bill was signed into law by Governor Rick Perry.)**	Yes. Study conducted by Texas Department of Insurance, PRIOR to introduction of bill, at the request of Governor Rick Perry.	Study found, "The implication of reducing patient out-of-pocket costs for pharmacy benefits is that costs are effectively shifted from

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Texas, CONTINUED…			the patient to health plans. **The cost of implementing chemotherapy parity is estimated at less than $0.50 per member per month in most cases,** although estimate can increase to $1.30 per member per month in cases where an enrollee faces high cost sharing requirements for pharmacy benefits and low cost sharing requirements for medical benefits."
Vermont	April 1, 2010	Yes, an analysis was conducted by the Vermont Department of Banking, Insurance, Securities and Health Care Administration (BISHCA).	Final BISHCA analysis concluded, "The Department has not received information indicating that mandating coverage for orally administered anticancer medications will significantly impact premiums.
Virginia	Passed in March 2012; Implemented on July 1, 2014.	Fiscal impact study conducted by the VA Dept. of Human Resource Management (DHRM) & Dept. of Planning & Budget	Bill implementation would NOT create significant fiscal implications for the Commonwealth of Virginia.
Washington (State)	January 1, 2012	Review conducted by Washington Department of Insurance.	Review found a nominal increase in premiums of 0.2% as result of enactment of oral chemotherapy parity law.
Wisconsin	January 1, 2015	Bill reviewed by Wisconsin Office of the Commissioner of Insurance (OCI).	Deemed to NOT be a mandate by OCI.

Examples of Administration Costs Associated with IV/Infused Chemotherapy

CPT Code	Description	Average Reimbursement
96360	Hydration iv infusion, initial	$59.43
96361	Hydration iv infusion, add-on	$15.98
96365	Ther/proph/diag iv infusion, initial	$73.72
96366	Ther/proph/diag iv infusion add-on	$22.61
96367	Tx/proph/dg additional sequence iv infusion	$34.12
96368	Ther/diag concurrent infusion	$20.17
96372	Ther/proph/diag injtial, sc/im	$24.00
96374	Ther/proph/diag injtial, iv push	$58.03
96375	Tx/pro/dx injtial new drug add-on	$23.65
96401	Chemo, anti-neopl, sq/im	$75.75
96402	Chemo hormon antineopl sq/im	$36.21
96409	Chemo, iv push, single drug	$117.17
96411	Chemo, iv push, addl drug	$65.70
96413	Chemo, iv infusion, 1 hr	$151.68
96415	Chemo, iv infusion, addl hr	$32.37
96416	Chemo prolong infuse w/pump	$167.58
96417	Chemo iv infusion each additional sequence	$75.12
96450	Chemotherapy, into CNS	$226.35
96521	Refill/maintenance, portable pump	$138.08
96523	Irrigation drug delivery device	$26.43
96542	Chemotherapy injection	$143.75

CPT (Current Procedural Terminology) codes are numbers assigned to every task and service a medical practitioner may provide to a patient including medical, surgical and diagnostic services. They are then used by insurers to determine the amount of reimbursement that a practitioner will receive from an insurer. In IV/infused chemotherapy, these costs would be incurred in addition to the cost of the drug itself. Health care providers utilize multiple CPT codes each time a patient undergoes an infusion.

**It is important to note that each health care facility negotiates its own reimbursement rates with health insurers. These average reimbursement rates listed are based on Medicare reimbursement rates. As the largest U.S. purchaser and regulator of health care, Medicare exerts a major influence on the rest of the health care system. Its reimbursement and coverage policies have been widely adopted by private insurers and other public programs.*

Benefits of Oral Anti-Cancer Therapies

Studies show that oral anti-cancer therapies, when compared with those administered intravenously, not only help decrease overall health care costs, but they also improve quality of life and reduce patients work loss costs. Despite these benefits, health plans often require higher cost-sharing for oral therapies than they do for IV therapies. Legislation is needed to ensure that cost-sharing does not limit patient access to these life-saving therapies that save the health care system money.

Background

The treatment of cancer is improving due in large part to new advancements in therapies. Patients are no longer limited to treatment via infusion as many anti-cancer therapies are now available in pill form. Oral anti-cancer therapies are becoming the treatment of choice for physicians and patients and are the only effective treatment option for some cancer patients. They are saving the health care system money, in addition to providing patients with a better quality of life. However, patients have difficulty accessing oral therapies because health plans often require higher cost-sharing for them than they do for IV chemotherapy.

Higher co-payments, co-insurance and deductibles result from insurance benefit design. Insurance companies' cost-sharing policies for cancer therapies have not adapted to the introduction of new, innovative oral medicines and continue to encourage the use of IV over oral therapies. To avoid intrusion on the physician/patient relationship and ensure patients receive the treatment deemed most appropriate by their doctor, health plans should not require different cost-sharing amounts for the oral and IV therapies that they cover.

Comparative Analysis

Oral anti-cancer therapies have a number of unique benefits. They not only help reduce overall costs but also improve patient quality of life:

- Direct Medical Costs: Treatments associated with IV administration have high direct medical costs. Costs include IV supplies, such as needles, in addition to personnel costs, such as physicians and nurses. Other visit- related costs may include lab tests, facility overhead and chemotherapy assessments. It has been estimated that IV treatments cost $47 more a day or $17,000 more annually than oral treatments.[9]

- Direct Non-Medical Costs: IV drug administration requires patients and caregivers to travel to facilities, which may result in additional costs, such as parking and other travel related costs.

Cost of IV Therapies Per Administration

Direct Medical Costs Per Chemotherapy Administration	
Total Personnel & Supplies*	$104-$638[1]
IV Supplies	$10-$77[2]
Personnel Supplies	$89-$311[3]
Direct Non-Medical, Work Loss and Time Related Costs Per Chemotherapy Administration	
Travel Costs	$10-$14[4]
Patient Work Loss &Time Related Costs	
Chemotherapy	89-310 Minutes[5]
Travel Time	38-64 Minutes[6]
Value	$33-$98[7]
Caregiver Time Related Costs	126-224 Minutes[8]

*Components do not sum to total, as former and latter were based on data from different studies

- Work Loss and Time Related Costs: Oral therapies allow patients to spend less time in care facilities. Time spent at care facilities may result in lost earnings for patients and their caregivers in addition to added expenses. Employers may also face costs associated with replacing workers and short term disability.

- Clinical Outcomes: While patients may experience adverse drug reactions for any therapy, whether it's IV or oral, patients taking IV therapies may experience infusion or injection-site reactions as well.

- Patient Perspectives: Cancer patients may suffer from a number of symptoms that impact everyday life, including pain, fatigue, appetite loss and nausea. Patients overwhelmingly prefer oral treatments over IV treatments as they minimize disruptions to daily living.[10]

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New Study Shows Cost Savings of Oral Cancer Therapies

COST STUDY BACKGROUND

A study published online in the *Journal of Medical Economics* on January 3, 2013[1] **compared overall costs of treatment for intravenous (IV) and oral therapies** used in relapsed/refractory Multiple Myeloma.[2]

In the study, researchers calculated total treatment costs for two commonly prescribed regimens for relapsed/refractory multiple myeloma over the course of one year. One regimen was administered intravenously at the doctor's office/infusion center, while the other included two medications which are taken orally in a pill form, often at home. Total treatment costs included:

- **Drug Costs** – the cost of the brand name drugs[3], at rates commonly paid by CMS and private health plans.
- **Direct Medical Costs** –the cost of office visits, drug administration, laboratory tests, and administration of any pre-packaged fluids/electrolytes to keep patients hydrated during treatment.
- **Adverse Event Management** - the cost to manage any major adverse events that commonly occur during treatment, such as anemia, pneumonia, or a significant reduction in infection-fighting white blood cells.

AUTHORS' CONCLUSIONS

TOTAL TREATMENT COSTS were higher for the IV therapy, even though the drug costs were about the same for the IV and oral therapies that were compared.

ANNUAL TREATMENT COSTS for the IV regimen were over $17,000 higher than the costs for the oral regimen, or approximately $47 higher per day.

DIRECT MEDICAL COSTS WERE RESPONSIBLE for the higher cost of care for the IV treatment. Total direct medical costs were some $5,000 higher per patient for the IV regimen, or approximately $35 higher per patient per day.

ENSURING PATIENT ACCESS TO ORAL THERAPIES SAVES MONEY

- This study demonstrates that **oral therapies can save the health care system money**. Oral cancer therapies are also more convenient for the patient and can have fewer debilitating side effects. For these reasons, they are often the treatment of choice. In some cases, there is no other choice - an oral medication may be the only effective treatment option available.
- Unfortunately, **cancer patients can face significantly higher out-of-pocket costs if their treatment is taken orally rather than intravenously**. The problem is out-of-date insurance benefit design. Some health insurance companies have not adapted benefit design to ensure patients have access to innovative oral cancer therapies, even if they are more medically appropriate or, as in this case, can save the health plan money.
- To provide patients access to life-saving therapies and create savings for the overall health care system, legislation should be approved to require **health plans that cover cancer treatments to do so equally for IV and oral therapies.**

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[1] *Durie BGM, Binder G, Pashos CL, Khan ZM, Hussein MA, Borrello I. Total cost comparison in relapsed/refractory multiple myeloma. Journal of Medical Economics. Epub 2013Jan 3.*

[2] *Relapsed/refractory Multiple Myeloma refers to cancer of the plasma cells in the blood in which there is a reappearance of signs and symptoms of the disease after a period of improvement (relapsed) or that the cancer is unresponsive to standard treatments (refractory)*

[3] *Because one of the drugs in the oral regimen is generic, the cost was considered negligible and not included.*

PRIME THERAPEUTICS SPECIALTY PHARMACY™

Case Study

Benefit design impacts specialty care

Study finds one in six cancer patients with high out-of-pocket costs do not fill prescription

BACKGROUND: While specialty drugs are most often injected or infused, cancer drugs taken orally are an exception to this rule. Oral oncology drugs are very expensive and often require complex care. For these specialty drugs, non-adherence can be life-threatening.

Oral oncology is fastest growing specialty category

Oral oncology drug spend increased 18.9 percent in 2010 across Prime Therapeutics' (Prime's) book of business, making it the fastest growing specialty drug category. With these rapidly rising costs, plan sponsors are looking for opportunities to best manage spending. This sometimes results in shifting more of the cost burden to the member.

Some patients choose to not fill their prescription when faced with high out-of-pocket (OOP) costs. This is referred to as prescription *abandonment*.

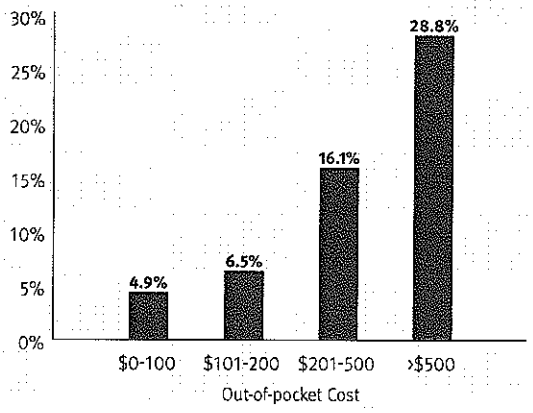
OOP costs affect drug abandonment

A study from Prime found one in six cancer patients with high OOP costs abandon their medication at the pharmacy. Patients with an OOP cost greater than $200 were at least three times more likely to not fill their prescription than those with OOP costs of $100 or less.

The results demonstrate that benefit design can have a powerful effect on prescription abandonment rates.

Prime recommends a member share maximum for specialty drugs to help prevent prescription abandonment.

Oral cancer therapy prescription abandonment rate



continued

Smart pharmacy management helps prevent abandonment, reduce waste

Saving pharmacy dollars at the expense of greater medical costs is not an effective cost management strategy. This is why Prime recommends setting a maximum member cost share of $100 for preferred specialty drugs, to prevent prescription abandonment and support medication adherence.

Waste is another significant concern in oral oncology. Cancer drugs often have undesirable side effects, which can cause patients to stop taking medication prior to completing treatment. For select cancer drugs, splitting the prescription into two fills allows Prime to make certain patients can tolerate treatment prior to shipping the second fill. By eliminating waste, the split fill program results in savings of $2,000 to nearly $4,000 per prescription.

Managing costs across both benefits

Prime Therapeutics Specialty Pharmacy (Prime Specialty Pharmacy), helps plan sponsors manage the total cost of care across both the medical and pharmacy benefit. Prime Specialty Pharmacy works with plan sponsors to implement smart benefit designs and effective utilization management programs.

Patients are educated about the importance of medication adherence and receive active support in following prescribed drug regimens from disease-focused care management teams.

Study methods

- Population: Claims from seven million members across eight Blue Cross and Blue Shield Plans were reviewed to identify members with a new claim for an oral oncology medication
- Timeframe: July 2006 through June 2008
- Definition of abandonment: claim that was subsequently reversed with no evidence of a paid claim within the following 90 days

Smart management of oral oncology drugs should focus on reducing costs without negatively affecting patient care. As oral oncology medications work to halt the progression of cancer, it is essential for patients to follow their prescribed medication regimen in order to avoid potential future costly hospitalizations and medical procedures. This study suggests high out-of-pocket costs for these patients may have an adverse impact on patient care and therefore long-term costs.

References

[1] Prime Therapeutics *2010 Drug Trend Insights.*

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Qualified Health Plan (QHP) Webinar Series Frequently Asked Questions

Frequently Asked Questions (FAQs) # 10

Release Date: May 2, 2013

Essential Health Benefits (EHBs)

Q1: We would like confirmation that the reasonable assurance provision in the EHB preamble applies to both individual and small group coverage.

A1: Yes, issuers of both individual and small group plans off the Exchange must be reasonably assured that enrollees have obtained pediatric dental coverage through an Exchange-certified stand-alone dental plan.

Q2: If a state discovers a clerical error or discovers an omission in the EHB template, how does the state change it? If the state wants to change a "decision" previously made about EHBs, how does the state change it?

A2: Unfortunately, the benefits, limits, and explanations representing a summary of the benchmarks that is posted on CCIIO's website (http://cciio.cms.gov/resources/data/ehb.html) cannot be changed at this time. The add-in file that populates the Plans & Benefits template is derived from this information. Please use the "EHB Variance Reason" to identify benefits as "Additional EHB Benefit" that you feel are part of the benchmark.

Q3: How much of the plan design of the benchmark transfers over to other carriers - just things listed as EHBs in the CCIIO template, things that could be categorized as EHBs by individual carriers, or all benefits (including those listed as "other" in the CCIIO template)?

A3: Any benefits and services that the benchmark plan covers are considered EHB and other carriers must be sustainably equal to the benchmark. See 45 CFR 156.115(a)(1).

Q4: Since carriers cannot substitute benefits across categories, categorization of benefits in the benchmark plan is important. What authority does the state have (or not have) to adjust categorization of benefits?

A4: Enforcing states have the authority to categorize the benefits. In the preamble to the final rule on EHB, at 78 FR 12843 we noted that states maintain flexibility in defining benefits within the 10 statutory categories.

Please Note: This is a partial listing; some questions may be combined or removed.

State Mandates

Q40: If a state enacts a new requirement that issuers that provide coverage of intravenous (IV) chemotherapy must cover oral chemotherapy at parity, does the state have to defray the cost?

A40: No. We do not consider such payment parity bills to create a requirement to cover a new benefit. In addition, in the preamble to the final rule on EHB at 78 FR 12845, we stated that plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB.

Q41: If a state enacts a new requirement for applied behavioral analysis (ABA) therapy, is that a benefit in excess of EHB, or can ABA be considered EHB because it is a service specific to an EHB category (falls within habilitative or mental health including behavioral health treatment)?

A41: *Defining* habilitative services would not result in a mandate, but *requiring* specific treatments/benefits, including ABA, creates a new mandate. Below is an example of a definition of habilitative services and a mandate for services, for illustrative purposes.

Example of definition - Habilitative benefits for purposes of the state's EHB benchmark plan are defined as follows: "Habilitative services are services that help a person retain, learn, or improve skills and functioning for daily living that are offered in parity with, and in addition to, any rehabilitative services offered in the state's EHB benchmark plan. Parity in this context means of like type and substantially equivalent in scope, amount, and duration."

Example of mandate – A bill requires private insurance companies to provide coverage under group health insurance policies for psychiatric care; psychological care; habilitative or rehabilitative care (including ABA therapy); therapeutic; and pharmacy care to children who have been diagnosed with autism spectrum disorder (ASD).

Please Note: This is a partial listing; some questions may be combined or removed.

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Statement in Support of SB625
Patient Cost-Sharing for Oral Anti-Cancer Treatments
Senate Insurance Committee – January 27, 2016

Oral therapies: a cornerstone in cancer treatment
For many years, intravenous (IV) delivery was the primary method for administering the medicines used to treat cancer but, in recent years, orally-administered medicines have increased in prevalence. In fact, for many cancers, an oral treatment is the standard of care and, in some cases, an oral therapy is the ***only*** available treatment option. This marks a major trend in cancer treatment: of the cancer drugs currently under development, estimates project that up to 35% will be available in pill format only.[i]

Disparities in coverage for oral therapies limit patient access
But unfortunately, health plans have not kept pace with this development, as high cost-sharing requirements prohibit many patients from accessing oral therapies. This contrasts sharply with the cost-sharing rules that have typically applied to IV-administered cancer treatments. For IV therapies – which traditionally have been covered under a plan's medical benefit – the typical cost-share is a flat co-pay of a moderate amount. Oral therapies, however, are usually covered under a plan's pharmacy benefit, where patients are commonly required to pay coinsurance. A percentage of the actual price of a medication, coinsurance can range as high as 50%, leading to a potential cost-share in the thousands of dollars for a single month's supply of a medication.

Such high cost-sharing forces patients to make impossible choices between paying for a medically necessary treatment or risking the family's financial stability. High cost-sharing also drives many patients to alter the prescribed treatment regimen: three out of seven cancer patients report skipping doses or cutting pills, as a result of financial pressures.[ii] In other cases, patients have stopped taking their pills altogether. According to one recent study, when a cost-share exceeds $500, nearly 25% of patients abandon their treatment regimen.[iii] Abandonment can lead to costly hospitalizations, the need for additional treatment, and disease progression.

A fair and balanced solution: SB625
The Leukemia & Lymphoma Society (LLS) applauds Sen. Geoff Hansen for his introduction of SB625, which would prohibit health plans from requiring cancer patients to pay an out-of-pocket cost for an oral therapy that is higher than the out-of-pocket required for an IV-administered cancer treatment. It's a simple solution, intended to ensure that patients can reliably expect fair and consistent coverage for cancer treatment, even when those treatments happen to come in the form of pill.

As of today, forty states and the District of Columbia have enacted a smilar law, as governors and legislators on both sides of the aisle and all across the country have come to recognize the very real

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Statement in Support of SB1025

Patient Cost-Sharing for Oral Anti-Cancer Treatments

Senate Insurance Committee – January 21, 2016

Oral chemotherapies a convenient alternative to cancer treatment

For many years, intravenous (IV) chemotherapy was the primary method for administering the medicines used to treat cancer but, in recent years, orally-administered medicines have increased in prevalence. In fact, for many cancers, an oral treatment is the standard of care and, in some cases, an oral therapy is the only available treatment option. This marks a major trend in cancer treatment as the cancer drugs currently under development, estimated at up to 375 will be available in pill form only.[1]

Insurance is necessary for oral therapies just as it is for IV therapies

Just as importantly, health plans have not kept pace with this development, as high cost-sharing requirements prohibit many patients from accessing oral therapies. This contrasts sharply with the cost-sharing rules that have typically applied to IV-administered cancer treatments. For IV therapies – which traditionally have been covered under a plan's medical benefit – the typical cost-share is a flat copay of a moderate amount. Oral therapies, however, are usually covered under a plan's pharmacy benefit, where patients are commonly required to pay coinsurance – a percentage of the actual price of a medication. Coinsurance can range as high as 50%, leading to a potential cost-share in the thousands of dollars for a single month's supply of a medication.

Such high cost-sharing forces patients to make impossible choices between paying for a medically necessary treatment or risk to the family's financial stability. High cost-sharing also drives many patients to seek the prescribed treatment with no share of cost or a cost-share equal to a copay or coinsurance pills, as a result of financial pressure.[2] In other cases, patients have stopped taking their pills altogether. According to one recent study, when a cost-share exceeded $500, only 25% of patients remained their treatment regimen.[3] Abandonment can lead to costly hospitalizations, the need for additional or more intensive treatments.

A patient-focused solution: SB1025

The Leukemia & Lymphoma Society (LLS) applauds Sen. Cleveland Hansen for his introduction of SB1025 which would prohibit health plans from requiring cancer patients to pay an out-of-pocket cost for an oral therapy that is higher than the cost-share required for a IV-administered cancer treatment. This is a simple solution, intended to ensure that patients can actually expect fair and consistent coverage for cancer treatment, and not have their treatment decisions impacted by a cost-share gap.

As of today, Iowa and the District of Columbia have passed a similar law, as [illegible] and legislation is in the offing in [illegible] states. We are [illegible] to [illegible] for [illegible] and [illegible]

[illegible]
[illegible]

barrier that this issue imposes on patients living with cancer. The existence of forty very similar laws also indicates that policymakers view the approach captured in this bill as the ***right*** solution. LLS is hopeful that lawmakers in Michigan will similarely embrace SB625, not only because it offers meaningful imrovements in access to care but also because it adopts an approach that is fair and balanced:

- **This bill is expected to have little-to-no impact on premiums.** This can be observed already in the forty states (plus the District of Columbia) where parity bills have been enacted: none of these states have documented a statistically significant increase in premiums as a result of these laws.
- **This bill will make tremendous improvements in access to care.** Under the Affordable Care Act, certain health plans must comply with an annual out-of-pocket maximum. This cap (set at $6,850 for an individual in 2016) is intended to limit the total out-of-pockets costs that a patient can be required to pay in the course of a single year. But an ***annual*** maximum offers little value to a patient facing a ***monthly*** financial hardship – for example, a $1,200 cost-share for one month's supply of a single medication – which cancer patients often encounter at the very start of their plan year. Thus many cancer patients continue to face serious financial strain as a result of the cost-share for their care. This bill would address that problem for many patients in Michigan.
- **This bill is not a mandate.** SB625 would apply only to health plans that already offer coverage for medications used to treat cancer – meaning, this bill does not require the coverage of a new benefit or service.

At LLS, our mission is to find cures for leukemia, lymphoma, Hodgkin's disease, and myeloma, and to ensure that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. We urge the committee to help advance that mission by supporting SB625.

With questions or concerns, please contact:

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The Leukemia & Lymphoma Society
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914.420.0135

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[i] Geynissman, DM and Wickersham, KE. "Adherence to Targeted Oral Anticancer Medications." *Discovery Medicine*, 2014: 17, no. 095.
[ii] Zullig, LL, Peppercorn, JM, et al. "Financial Distress, Use of Cost-Coping Strategies, and Adherence to Prescription Medication Among Patients With Cancer." *Journal of Oncology Practice*, 2013: vol. 9, issue 6s.
[iii] Streeter, SB, Schwartzberg, L, and Johnsrud, M. "Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions." *American Journal of Managed Care*, 2011: 175, 5 spec no: SP38-SP44.

MSHO Michigan Society of Hematology & Oncology ASCO®

Statement of Phil Stella, MD

Michigan Senate Insurance Committee
Hearing on SB 625

January 27, 2016

Chairman Hune, Vice Chair Brandenburg, and members of the committee, thank you for the opportunity to provide testimony today in strong support of SB 625 on behalf of the Michigan Society of Hematology and Oncology (MSHO) and the American Society for Clinical Oncology (ASCO). I am Dr. Phil Stella, an oncologist from Ann Arbor Michigan, and the Chair of the ASCO Government Relations Committee.

Dedicated to promoting exemplary care for patients with cancer and/or blood disorders through advocacy, education and research, MSHO represents over 2,000 healthcare professionals in private practice, academic medical centers and hospital-based clinics throughout the state. With nearly 40,000 members, ASCO's mission is conquering cancer though research, education, and promotion of the highest quality patient care.

SB 625 would help ensure that similar policies apply to patient cost-sharing for both traditional intravenous cancer drugs and oral cancer drugs. Forty states and the District of Columbia have enacted similar laws, and with your help Michigan can be the next state to take this important step.

Thanks to scientific breakthroughs, today medical oncologists have opportunities to treat cancer patients with oral and other self-administered anticancer medications rather than just with traditional intravenous (IV) or injected cancer drugs. Oral cancer drugs may represent the only or best treatment option in some instances. Oral cancer drugs play an increasingly important role in my day-to-day care of cancer patients.

However, some health plans impose significantly higher cost sharing requirements on cancer patients for oral cancer drugs than for IV or injected cancer drugs. In most cases this is because traditional cancer drugs are covered under the medical benefit of most insurance plans and oral cancer drugs are often covered under the outpatient drug benefit. The cost sharing burden imposed on patients can create insurmountable financial barriers for cancer patients who need access to oral cancer medications.

Ensuring that cancer patients have meaningful access to oral cancer drugs is an issue of critical clinical importance. This is not merely an issue of convenience for cancer patients or medical oncologists.

I strongly urge the committee to pass SB 625. It is the right thing to do for Michigan's cancer patients.

AIM
AT MELANOMA
FOUNDATION
Reshaping the Future Together
AIMatMelanoma.org

January 27, 2016

Re: Support SB 625 (Hansen); Access To Oral Cancer Treatments

Dear Senator Hune and Members of the Senate Insurance Committee;

AIM at Melanoma is the largest international melanoma foundation focused on melanoma research, education, awareness, and legislation. AIM urges you to support SB 625 (Hansen), which would ensure that cancer patients have access to oral anticancer treatments that are covered by their health plan or insurance.

Melanoma is the fastest growing cancer in the United States and worldwide. If not caught early, melanoma is known to be the most deadly of all skin cancers. Some of the most promising new FDA-approved melanoma treatments are oral treatments. For melanoma patients who test positive for the BRAF mutation, about 50% of late stage melanoma patients, one of the standards of care is to be treated with one of these oral treatments.

Given the choice, patients typically prefer to take oral drugs as opposed to an infusion due to the comfort, convenience and efficacy of oral medicines. However, in many cases, oral treatments are cost prohibitive because of the substantial co-pays and deductibles. Patients, families and their medical providers should be making treatment decisions based on what's best for the patient, not because of the cost.

For these reasons, AIM urges you to support this life-saving measure that would provide access to all appropriate treatments for cancer patients.

Thank you for your time and consideration.

Sincerely,

Samantha Guild

Samantha Guild
AIM at Melanoma
Reshaping the Future Together
415-305-0060

TESTIMONY IN SUPPORT OF SB 625

MICHIGAN SENATE INSURANCE COMMITTEE

JANUARY 27, 2016

My name is Terry O'Donnell. I was born in the city of Detroit and currently reside in the city of Troy, Michigan. I have lived in southeast Michigan for almost all of my life.

I have been involved with the Leukemia & Lymphoma Society of Michigan (LLS) for the last 20 years and appear here today thanks to their request to represent them. I have been a mentor to newly diagnosed leukemia patients through LLS's First Connection Program, participated in their annual educational conferences, conducted bone marrow registry events, and been involved in some capacity with each of its annual fundraising campaigns, from Light the Night to the Man and Woman of the Year to its very successful and widely known Team in Training program.

In late November of 1993, I was a healthy, athletic young man, accustomed to running 2 to 3 miles per day, and frequently ran 5K and 10K races sponsored by a variety of charitable and civic entities. That all changed overnight when I was stricken with acute hairy cell leukemia. Within just four days, I went from enjoying my daily run to being hospitalized and in a shockingly unexpected fight for my life.

In those four days, I observed and endured an increasing array of bizarre changes rapidly happening to my body. Eerie muscle pains and a fever were soon followed by large inexplicable bruises on my arms and legs, bleeding gums, swollen lymph nodes, a rapidly expanding spleen, and other changes best left unmentioned. After seeing my primary care physician and having some blood tests done, I received a phone call from my doctor asking me how quickly could I get to the Emergency Room at Beaumont Hospital in Royal Oak. Living close by, I was there in about 15 minutes and had a doctor who specialized in hematology oncology, blood cancers, asking me if he could conduct a bone marrow biopsy on me, right there in the ER, because none of the surgical rooms where those were normally performed were available. Everything was happening so quickly and my world was turning upside down. I couldn't have known or imagined how much or for how long it would remain that way.

Being told that I had an acute leukemia was as much of a shock as you might imagine. But that wasn't the biggest shock I was in for. I was simultaneously told that I had a type of leukemia called hairy cell, the rarest form of all the leukemias.

Furthermore, all the medical books and journals said hairy cell leukemia occurred only in the slower progressing chronic state and never in the acute state. But there was no mistake about it, mine was acute and raging fiercely.

To give me some assurance that there was something that could be done, the doctors informed me that there were a few drugs that had a good track record of success in treating the chronic form of my leukemia but that we'd have to be much more aggressive and amp up treatments right from the outset which, by the way, was right away. What did I have to lose except my life.

The first treatment plan did slow down the progression of the leukemia but after four weeks my body became intolerant to the drugs and we had to stop using them. That turn of events was perhaps more distressing than the onset of the leukemia and the troubling diagnosis. My doctor's first and best choice of treatment options was now off the table, it had been tried and failed.

Then I caught a huge break. The federal Food & Drug Administration (FDA) had approved the use of a new chemotherapy, leustatin, for the treatment of many leukemias and other blood cancers. It held more promise of a remission than any of the other chemotherapies that had been in use. Not surprisingly, I was the first person in Michigan to be treated with leustatin. It was a very tough chemotherapy with a long list of debilitating side effects that I experienced in a seemingly endless succession. Four months later and six months since the onset, my leukemia had been subdued into remission.

The reason that I recount my ordeal, with perhaps more detail and length than preferred, is because I learned from that experience how crucial to my survival was the fact that I maintained a positive frame of mind. Not a foolish hope or pie in the sky dream but a realistic and positive frame of mind imbued with the knowledge that my doctors were treating me with the best treatment options available. I can scarcely imagine how difficult it would have been to keep a positive frame of mind if I knew that I was receiving only the second or third choice of treatment options. That's what too many people are forced to cope with when they are unable to receive an oral

chemotherapy that is their best chance of putting their cancer into remission or beating it once and for all.

My remission lasted for a little over seven years and when it returned, I was fortunate that it was a slow progression. Needing to undergo treatment once again, my oncologist presented me with two treatment options in early 2002. The first was to be treated with the chemotherapy leustatin again and there was a high probability that would be sufficient to put my leukemia back into remission. The second option was to be treated with the chemotherapy leustatin but to follow it up with several months of additional treatment with another new drug, rituxan, that had shown a surprising amount of success in achieving remissions for people who had not had their leukemia go into remission when treated with leustatin. My oncologist's thinking was that the dual treatments might have a synergistic affect and could produce a longer and stronger remission. The downside to this second treatment option was that it would subject me to several additional months of treatment with a reduced immune system and the risks that would be involved in that condition.

Despite the risks, I chose the second treatment option, leustatin followed by rituxan, because I believed in my oncologist and that either I would benefit from the novel treatment plan or, at worst, something useful would be learned and that could move the field of knowledge closer to finding better methods of treatment or possibly even a cure. I'm happy to be here today, a little over 13 years in remission and counting, and continue to prove that my oncologist and that treatment plan were correct. In fact, it is now recognized as the protocol, the standard of care, for treating hairy cell leukemia, whether in the chronic or the acute state.

Even with the successes that I have experienced, it would be great if there was an oral chemotherapy that could accomplish the same result without all the side effects that I incurred, which were numerous, continuous, and debilitating. My first bout of leukemia put me out of work for eight months and the second bout for six months. The much more targeted treatments that oral chemotherapies provides people negates most of those affects and allows people to work, care for their children, and continue to lead productive and rewarding lives all the while battling their disease. The trend in the direction of more oral chemotherapies is continuing. Nearly half of all cancer drugs in

the development pipeline are oral chemotherapies. They are often cutting-edge therapies for which there is no IV (i.e., intravenous) equivalent. Thus, to deny access to oral chemotherapy treatments means that doctors are left to prescribe less than ideal treatments and patients must endure treatments that do not give the best chance of surviving their disease.

Since oral chemotherapies were switched in 2008 to the prescription portion of health insurance plans, I have spoken with dozens of hematology oncologists in Michigan who have told me that 25% of their patients for whom an oral chemotherapy would be their best treatment option aren't receiving it because they can't afford the amount of the monthly co-pay or co-insurance. It has to be excruciating to undergo treatment and keep a positive frame of mind when you know it isn't the best option available. Fighting cancer is a tough enough battle without having one arm tied behind your back.

In order to pay for an oral chemotherapy, people that I know personally have had to (a) borrow money from family and friends, (b) take out a reverse mortgage on their home during their golden years, and (c) conduct in-person or online fundraising campaigns, dinners, or auctions. It's one thing to resort to those measures for experimental medical procedures and care but not for access to ordinary oral chemotherapy treatments.

Access to oral chemotherapies is a real problem and the cost is measured in the lives of real people. Today, 40 states and the District of Columbia have already passed legislation authorizing exactly what SB. 625 would accomplish. The time for it to happen in Michigan is now. Thank you.

Respectfully submitted,

J. Terence (Terry) O'Donnell

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Michigan Senate District 13