

#CareDenied

**CANCER CARE**

**DENIED**

The Broken State of  
Patient Access to  
Proton Therapy

 **Alliance for  
Proton Therapy Access**



#CareDenied

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## **ABOUT THE ALLIANCE FOR PROTON THERAPY ACCESS**

The Alliance for Proton Therapy Access is an advocacy organization comprised of a growing community of patients, families, caregivers, physicians and industry partners working together to make sure all cancer patients seeking proton therapy receive fair and timely payment decisions from their health insurers.

🌐 [www.AllianceforProtonTherapy.org](http://www.AllianceforProtonTherapy.org)



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# THE CASE FOR REFORMING A BROKEN INSURANCE SYSTEM

A cancer diagnosis is overwhelming enough, but when Dianne Weber experienced a recurrence of anal cancer after five years of remission, she and her husband, Jack, found themselves on the losing end of a power imbalance that epitomizes the broken state of our nation's insurance system.

Treatment for Dianne's second bout with cancer began with four months of chemotherapy. A large tumor remained, however, and doctors told her that conventional radiation was not an option because she had been treated with it the last time and further radiation would damage nearby organs. Instead, they prescribed proton beam therapy because it is precise enough to hit the cancer cells while minimizing excess radiation exposure to her small bowel, liver, and colon.

Dianne prepared to move forward with proton treatment until she, Jack, and their medical team were stunned to learn that her insurer, Anthem Blue Cross and Blue Shield, refused to pay, saying the treatment was "not medically necessary," and "experimental and without justification." Jack and Dianne were appalled to learn that Anthem justified its denial of payment based on guidelines from the American Society for Radiation Oncology (ASTRO) that were four years old and had been updated to include her diagnosis. They also learned that the outside medical utilization vendor who reviewed Dianne's case was a wholly-owned subsidiary of Anthem— not an independent entity as Anthem representatives suggested.

The couple filed an appeal, only to be turned down again. Jack devoted at least 100 hours of his time calling and writing anyone who might be able to help. Finally, in the middle of a press conference where Jack detailed their journey – including receiving statements from their insurer riddled with outdated, incorrect and misleading information –

the Webers learned that an independent review by the Virginia Bureau of Insurance had overturned their insurer's denial, and Dianne received approval to receive proton radiation treatment.

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*"I am pretty astute, I'm not financially destitute, I have connections, and I know how to fight. And that's exactly what I did. But there are a lot of people out there who don't have the connections, who don't have the money, who don't have doctors who care as much, and those people are the ones that are being hurt the most."*

**JACK WEBER**

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## CANCER TREATMENT SHOULDN'T BE A WAITING GAME

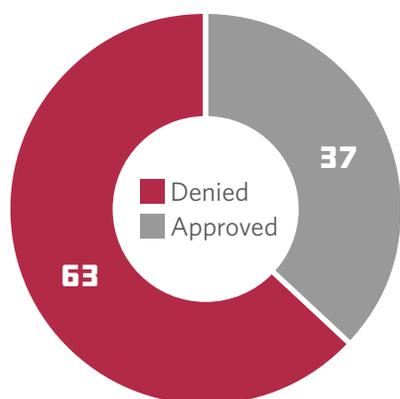
Dianne and Jack's experience with their insurer is far from unique. Too many cancer patients are delivered a life-threatening diagnosis, only to experience additional anxiety when their insurer cavalierly rejects their physician-recommended treatment.

The recent story out of California demonstrates a particularly egregious betrayal of customers' trust by an insurance provider. The California insurance commissioner is investigating Aetna after its former medical director admitted he never reviewed patient information when making treatment approval or denial decisions.

Patient experience data shared with the Alliance for Proton Therapy Access (the Alliance) by several U.S. proton therapy centers revealed that seemingly random denials are common. Nearly two-thirds of their patients who were prescribed proton therapy were initially denied by commercial (non-governmental) insurers.

■ Insurers say “NO” to most physician requests to treat cancer patients with proton radiation therapy

Percent of oncologists’ requests for proton therapy that are **Denied** or **Approved**



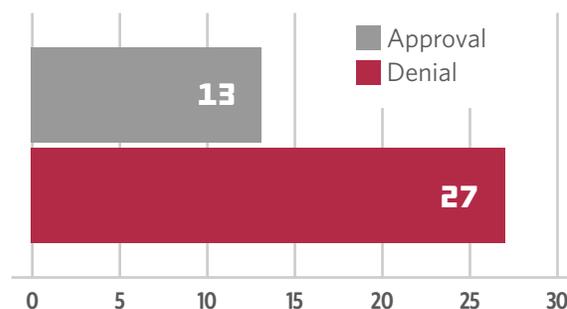
Data from 1,100 cancer patients provided to the Alliance by U.S. proton therapy centers

Every day, physicians report spending hours trying to get their patients’ proton treatment approved on appeal – too often arguing their case with insurance representatives who know little or nothing about proton therapy. Cancer patients wait days, weeks, or even months for an opaque appeal process to play out, while their cancer and anxiety grow.

Patient data revealed patients wait an average of nearly three weeks (13 work days) for successful appeals. Cancer patients who were ultimately denied waited an average of almost six weeks (27 work days) for their insurers’ final, heartbreaking decision. These delays heighten patients’ anxiety even more – during a time when their emotional and physical

■ After receiving a cancer diagnosis, patients who appeal their insurer’s proton therapy denial can wait weeks or months before receiving a final determination

Number of working days between filing appeal and final **Approval** or **Denial**



Data from 773 cancer patients provided to the Alliance by U.S. proton therapy centers

energy should be focused on fighting cancer – which is actually growing, further harming the patient.

Some patients and their families – like Dianne and Jack and others featured in this report – are finding that telling their story in the media is a necessary step to influence their insurers to reverse a denial.

Faced with a progressing, life-threatening disease, other cancer patients start proton radiation treatment without their insurer’s approval and spend tens or hundreds of thousands of dollars out of their own pocket if they are not successful in their appeals.

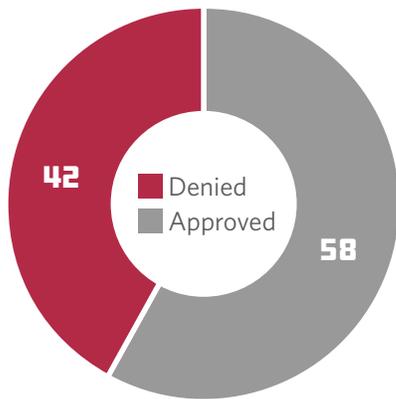
But many patients do not have the financial resources or wherewithal to pursue either of these strategies; they grow weary of fighting their insurer while cancer grows inside them and forego doctor-recommended proton radiation for treatment that may be less effective, come with greater health risks, or result in a lower quality of life.

In the end, the balance of power is tilted too heavily toward insurers – after weeks of anxiety-filled waiting, fewer than six in ten patients are approved to receive proton therapy.

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■ Patients whose physicians recommend proton therapy are ultimately denied access more than 4 times out of 10.

Percent of patients seeking proton therapy who are ultimately **Denied** or **Approved**



Data from 1,100 cancer patients provided to the Alliance by U.S. proton therapy centers

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## BREAKING DOWN THE BARRIERS TO FAIR, APPROPRIATE ACCESS

There is no reasonable explanation for these excruciating delays and high rate of denials. Proton radiation is an FDA-cleared treatment that is routinely approved for pediatric patients and by Medicare and recommended by top researchers and medical associations as the best treatment for several kinds of cancer (see Appendix A, Proton Therapy Facts). Utilizing highly targeted proton radiation preserves healthy tissue and reduces the chance of secondary cancers later in life. **Isn't this a good enough reason for cancer patients of all ages to have fair and timely access to proton radiation therapy?**

In 2017, the Alliance set out to understand why insurance companies so often deny proton therapy despite oncologists' expert recommendations. [We surveyed 108 national insurers and radiation oncology benefit management companies to find out how they make decisions – and 103 opted not to share any information.](#)

The unwillingness of insurers to be transparent about their review, appeals, and payment decision processes creates an unfair power imbalance. Insurance providers are increasingly hiring third-party radiation oncology benefit management companies to assist in evaluating and approving prescribed radiation treatment, which adds another level of opacity but should absolutely not let insurers off the hook for their responsibility to their customers.

America's cancer patients deserve better than a broken review and appeals process that exacts such high financial, emotional, and health costs during one of the most urgent and vulnerable times of their lives.

## HOLDING INSURERS ACCOUNTABLE

A growing number of cancer patients and their families are taking the fight for a fair, timely insurance process public, demanding that the balance of power and medical decision making be shifted back toward patients and their physicians. They are calling for decision-makers – including state insurance commissioners and companies with self-funded group health plans – to fix the broken process by adopting and enforcing principles of a Cancer Patients' Timely Treatment Bill of Rights. These eight common-sense principles are detailed on page 12, and summarized below:

### Cancer Patients' Timely Treatment Bill of Rights: What All Cancer Patients Deserve

- ✓ **Fair, appropriate access to doctor-recommended treatment**, with approval/denial decisions made:
  - in a transparent process
  - based on accurate and up-to-date clinical criteria, and
  - appeals handled by a medically qualified expert in the type of cancer the patient is facing, and the specific type of treatment recommended
- ✓ **Timely access to treatment** with initial approval/denial decisions made within **1 day** – and appeals

settled no later than 5 days – from the initial request. State insurance commissioners review final denials and hand down a decision within 15 days

- ✓ **Enforcement mechanisms executed by insurance commissioners**, including:
  - automatic approval if an insurer fails to meet the 5-day timeline for expedited appeal
  - meaningful and substantial fines for repeated failure to provide fair, appropriate approvals
- ✓ **The same rights for cancer patients covered by employer self-funded plans**, which are not regulated by state insurance commissioners

The Cancer Patients’ Timely Treatment Bill of Rights is not revolutionary – it sets out reasonable expectations for treating an urgent, progressive, life-threatening disease. In fact, the Bill of Rights principles are consistent with regulations established by many state insurance commissioners. But too many patients’ stories point to a lack of enforcement and accountability. That’s why we also call on state insurance commissioners – whose job it is to protect healthcare consumers – to enforce these common-sense principles.

Many companies self-fund their employees’ health plans and as such, are not regulated by state insurance commissioners. In these cases, employers have the flexibility to provide the health care benefits their employees need. They also have the responsibility to ensure that their contracted insurance provider adheres to the same common-sense principles and provides transparent, timely, fair and appropriate access to doctor-recommended treatments.

## **PATIENT ADVOCATES RAISE THEIR VOICES**

Cancer patient advocates are speaking out and calling for change because they trust their physicians to recommend the best treatment for their cancer. And they believe they and their physicians deserve transparency, fairness, and timely responses when seeking approval for that treatment from insurers.

Megan Niese’s telling of her brother’s story has

a good outcome, but no thanks to their insurer. Megan is speaking out because she recognizes that many patients and their families are not able to pay for the treatment they know is needed when their insurer refuses it.

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*“My family learned the hard way that insurers really do put profits over patients after my 23-year-old brother was diagnosed with a brain tumor. Although doctors recommended proton therapy, our insurer denied payment, despite the many benefits it offered to a young man with a long life ahead of him. While he was ultimately able to access proton therapy, it was only after a payment plan was established with his proton center. Our insurer never wavered in its refusal to pay. This experience has opened our eyes to the power insurers have over patients when they need insurance the most. Sadly, too many insurers are turning their backs on cancer patients.”*

**MEGAN NIESE**

*Proton patient family member & Alliance Board member*

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Cathleen McBurney is another fierce advocate. Her experience demonstrates the ability of companies with self-funded plans to ensure employees and their families get the care they deserve.

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*“As the survivor of a rare, inoperable, Stage IV cancer, I am living proof of the value of proton therapy. My treatment was covered only because of our employer’s self-funded insurance policy, and they carried the financial burden of my treatment. Others aren’t so lucky, which is why I fight for those who have only enough fight left for survival.”*

**CATHLEEN MCBURNEY**

*Proton therapy patient & Alliance Board member*

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# CHRONICLE OF A BROKEN PROCESS – ONE PATIENT’S STORY

Linda C. Thomas spent much of 2017 fighting two battles. The first was against a rare and aggressive granular cell cancer behind her left ear. The second was against her insurer. Following a diagnosis and subsequent surgery, Linda explored further treatment. An interdisciplinary team of head and neck cancer experts recommended a second surgery followed by six weeks of proton beam radiation that could attack remaining cancer cells while sparing her brain stem and other sensitive tissue from the effects of radiation.

Anthem Blue Cross Blue Shield denied Linda’s request for proton therapy, launching her into an appeals process that she described as “maddening.” Linda chronicled her countless hours spent on hold, tracking down paperwork, filling out appeals and pleading with Anthem for answers.



## DAY 1

I met with a team from the proton center and they submit an expedited authorization request for proton therapy. Anthem has 72 hours to answer our request.

## DAY 9

Surgery – big day. It’s been over a week and still no word from Anthem on my request for proton therapy.

## DAY 14

Well after the deadline, Anthem called the proton center to say they’re denying my treatment. **After waiting this long, I find out that an ER physician – NOT a radiation oncologist – reviewed my case.**

## DAY 17

I finally received my denial in writing so that we can submit my first-level expedited appeal.

## DAY 31

Twelve days after the deadline and many follow up calls later, I’m still waiting for a response from Anthem on my appeal.

## DAY 37

Anthem finally called my doctors to say they are upholding their original denial. Anthem continues to get away with violating federally mandated deadlines.

## DAY 41

I make the tough decision to borrow money from family and pay \$56,000 so I can start treatment.

#### **DAY 42**

“We understand an appeal was requested because you feel an MRI of your L-spine is medically necessary.” I think it is a joke when I finally receive a denial letter that doesn’t even correctly identify the treatment I requested. It’s clear my case has not received a full and fair review.

#### **DAY 49**

I am spending hours on the phone and computer every day, trying to get Anthem to answer questions about my denial. It’s like a part-time job.

#### **DAY 55**

The proton center submits my second-level appeal.

#### **DAY 66**

**Halfway done with treatment—got another Anthem denial.** Denials come quickly, while the documentation I need to appeal—faxes, letters, forms—all seem to get “lost.”

#### **DAY 73**

My doctors request an external review of my case – my last hope for access to treatment.

#### **DAY 76**

Good news today! With four days left of treatment, the external reviewers overturn the denial and rule that Anthem will have to approve my proton therapy treatment.

#### **DAY 80**

I finished treatment today, and Hurricane Harvey hit Houston – relieved to be heading home.

#### **DAY 83**

At home in Indiana, Hurricane Anthem is still swirling. Over the next few weeks, I receive a letter for each of my 30 proton treatment claims stating Anthem will delay payment while their medical team reviews my case (yet again).

## **EPILOGUE**

As of November 2017, Linda was declared cancer free and looking forward to the holidays when she received a letter from Anthem that exemplifies the absurdity of this entire process. Dated in August, the letter thanked Linda for submitting a second-level appeal. It promised she would receive further written communications, but—in true Anthem fashion—none arrived.

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*“The totality of this experience has shown me just how sick the health insurance industry has become. It is inexcusable that health insurers can act in bad faith with no repercussions, while critically ill and compromised patients are expected to wage battle and navigate the deliberately confusing bureaucratic appeals process for the care that is rightly theirs. While I was able to take a huge financial risk to protect my health, not all patients are able to do the same. What will become of them?”*

**LINDA C. THOMAS**

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# DELAYS AND DENIALS: PATIENTS SPEAK OUT

Linda's story is not unique. These brief profiles of patients who are speaking out about the broken insurance process represent just a fraction of cancer patients who every day are paying the emotional, financial, and health costs of review and appeals processes filled with needless delays, inexplicable errors, and, in the end, inappropriate denials of doctor-recommended cancer care.

*"My insurer - who should be, above all else, interested in my health - would have left me for dead. In short, fighting cancer is hard enough, I shouldn't have to also fight my health care provider."*

## DANIEL BAUDER



Virginia Beach, VA

Age: 53

Diagnosis:

Brain Cancer & Leukemia

Daniel's insurer repeatedly called proton treatment "experimental and investigational" and denied payment. Paying \$80,000 of his own

savings to begin treatment, the denial was eventually overturned after a six-month (183 day) fight and external review.

*"My family will recover from the financial hardships of paying out of pocket for the therapy, however, there are many more patients without the financial means to fund their own care, and who are dependent on their insurer and have nowhere else to turn."*

## VIVIAN HECKMAN



Clearwater, FL

Age: 60

Diagnosis: Lung Cancer

Vivian's family's self-funded insurance plan through her husband's employer denied payment for proton therapy, deeming the treatment

"experimental." She paid out of pocket more than \$100,000.

*"Despite the fact that proton therapy seems unattainable because of my insurer, my oncologist told us he wouldn't recommend traditional radiation therapy because proton therapy truly is my best shot at a long, healthy life."*

## ZACH RIZZUTO



Fort Myers, FL

Age: 37

Diagnosis:

Anaplastic astrocytoma

After being diagnosed with an aggressive brain cancer, Zach and his family soon learned his insurer denied payment. After his

denial was upheld by an independent external reviewer, they went to the media and launched a GoFundMe page to help fund his treatment.

*"I had no idea that my biggest fight would be with an insurance company. That was the last thing I was prepared for and I don't think anyone needs to have that fight."*

## MARCIA MCNANNAY



Palouse, WA

Age: 59

Diagnosis: Breast Cancer

After Marcia's breast cancer came out of remission in April 2017, her doctors recommended she get proton therapy because surgery, chemotherapy, and radiation

treatments were found to be ineffective for her. Marcia's insurance company refused to pay for the treatment or even pay for a second opinion. Her denial was eventually overturned after she hired a lawyer and spent four months fighting with her insurer.

*"I may work for NASA, but it doesn't take a rocket scientist to see that brain tumor patients and doctors should be launching a fight on cancer, not insurance appeals."*

### **DEREK WILLINGHAM**



Pearland, TX  
Age: 34  
Diagnosis: Oligodendroglioma

Derek's insurer denied payment for proton therapy twice after his doctors recommended it following surgery to remove 40 percent of his brain tumor. He was told he would

have to pay \$100,000 out-of-pocket to receive the treatment. Only after his family decided to take his story to the local media did his insurer reopen his case and approve his treatment.

*"We need to stand up and hold insurers accountable for ignoring qualified physicians' advice and blocking patient access to care. Not all patients have the know-how to fight their insurer."*

### **PAUL PENKE**



Omaha, Nebraska  
Age: 34

Diagnosis:  
Grade 3 Oligodendroglioma

Paul's insurer denied proton therapy through multiple appeals spanning three weeks. Paul went to his local media and the night his story aired, the insurer reversed its denial.

*"The additional cost would have been a drop in the bucket for a large insurance company. That seems like a worthwhile investment considering I'm a 23-year-old man in the prime of life."*

### **BRENT NEISE**



Columbus, OH  
Age: 23  
Diagnosis: Brain tumor

Brent's insurer denied payment and appealed to no avail. After fighting the insurance company for six weeks, the small window of time

Brent had to begin his next phase of treatment was closing, his family worked out a payment plan with the center so he could begin treatment.

*"When it comes to cancer treatment, disregard for facts and complex, drawn-out, and unfair insurance review and appeal processes are all too common."*

### **STEPHANIE WURDOCK LINDSEY**



Lexington, Kentucky  
Age: 31

Diagnosis:  
Adenoid Cystic Carcinoma

Stephanie's insurer denied her request for proton therapy three times; the final denial wasn't issued until two weeks after her initial claim was submitted. Thanks to an independent external review – and with the help of a personal connection to the insurance commissioner's office – her denial was overturned, and Stephanie received treatment.

*"If I had received proton therapy, I am confident I would not be suffering from these side effects and I would have maintained a much higher quality of life during and after treatment."*

### **MIKE HAGY**



Wichita Falls, Texas  
Age: 58  
Diagnosis:  
HPV Oropharyngeal Cancer

After Mike's insurer denied proton therapy and a two-week appeal process, he opted to move forward with IMRT because he didn't want to wait any longer to begin treatment. He suffers from side effects including weight gain and a thyroid condition that will require lifelong medication therapy.



## A CALL TO ACTION: CANCER PATIENTS' TIMELY TREATMENT BILL OF RIGHTS

**T**he Alliance is calling on state insurance commissioners to step up and enforce regulations already in place and adopt and enforce principles of the Cancer Patients' Timely Treatment Bill of Rights. By requiring insurance providers to adhere to common-sense practices and timelines and executing effective enforcement mechanisms to hold insurers accountable, state insurance commissioners can ensure cancer patients receive what they all deserve: fair, timely, and transparent access to cancer treatment.

# CANCER PATIENTS' TIMELY TREATMENT BILL OF RIGHTS:

## Principles to Ensure Fair, Timely, and Transparent Access to Cancer Treatment

Cancer patients and their doctors should be fighting *cancer*, not insurance companies. Unfortunately, too many cancer patients are battling restrictive, opaque, and unfair insurance review and appeal processes that drastically delay or make it impossible to receive treatments their doctors appropriately prescribe.

### The Cancer Patients' Timely Treatment Bill of Rights: What All Cancer Patients Deserve

- ✓ **Fair, appropriate access to doctor-recommended treatment**, with approval/denial decisions made:
  - in a transparent process
  - based on accurate and up-to-date clinical criteria, and
  - appeals handled by a medically qualified expert in the type of cancer the patient is facing, and the specific type of treatment recommended
  
- ✓ **Timely access to treatment** with initial approval/denial decisions made within **1 day** – and appeals settled no later than **5 days** – from the initial request. State insurance commissioners review final denials and hand down a decision within **15 days**
  
- ✓ **Enforcement mechanisms executed by insurance commissioners**, including:
  - automatic approval if insurer fails to meet 5-day timeline for expedited appeal
  - meaningful and substantial fines for repeated failure to provide fair, appropriate approvals
  
- ✓ **The same rights for cancer patients covered by employer self-funded plans**, which are not regulated by state insurance commissioners

## **FAIR ACCESS TO DOCTOR-RECOMMENDED TREATMENT**

### **PRINCIPLE #1**

Approval and denial determinations must be made in a transparent process and based on accurate and up-to-date clinical criteria, including current literature and recommendations of medical societies. Clinical information used for these determinations must be readily available to the prescribing physician, patient, and the public.

Because insurance companies often use third parties to help make approval or denial decisions, the relationship of these third parties, including the methodology used to select such vendors, payments made on a per case basis, the methodology used by the external vendor to review submitted case information, incentives for denial, if any, and the external reviewer's conflicts if any must be openly available for review in the public domain.

## **TIMELY ACCESS TO TREATMENT**

### **PRINCIPLE #2**

Cancer patients and their providers must be notified of a health plan's approval or denial determination within 24 hours after the initial request is made.

### **PRINCIPLE #3**

If an insurer questions the medical necessity or the experimental or investigational nature of a health care service and is planning to issue a denial, the insurer must first provide the recommending physician (within the one-day requirement) a meaningful opportunity to discuss the patient's treatment plan and the clinical basis for the insurer's denial with a physician reviewer. A lack of reviewer familiarization with the relevant data cannot be a basis for denial.

## **FAIR AND TIMELY EXPEDITED APPEALS**

### **PRINCIPLE #4**

The patient or a person acting on the patient's behalf, or the patient's physician may appeal any denial decision by telephone or in writing and the insurance company has four working days to act on that appeal.

### **PRINCIPLE #5**

The insurance company is required to use a board-certified medical oncologist, radiation oncologist, or surgical oncologist appropriately matched to the service being requested to make the decision on any expedited appeal.

### **PRINCIPLE #6**

A final decision on any appeal must be made within four working days. If an approval or denial determination has not been made on an expedited appeal at the end of business on the fourth day, the requested treatment shall be deemed approved.

## **ENFORCEMENT**

### **PRINCIPLE #7**

If a cancer patient has received a denial determination from his or her insurer, the patient may file a complaint with the state insurance commissioner.

The State insurance commissioner shall complete an investigation of the cancer patient's complaint within 15 working days based upon information provided by the patient, their physician, and the health plan; the health plan's review process, confirmation of the specific documents reviewed, and written findings of the review will be considered required submissions and must be provided immediately. If a health plan is found in violation of not providing either the appropriate documentation in a timely manner, or appropriate approvals for services that are determined to be safe, effective and covered treatment by other health plans within the industry, the insurance commissioner may do any or all of the following things:

- Order the insurer to approve the treatment immediately;
- Require the health plan to update their coverage policy as it relates to such treatments so other patients do not experience the same problem;
- Order the insurer to pay a meaningful and substantial fine if it is determined that the insurer has a pattern of regularly denying access to services that are determined to be safe, effective and covered treatment by other health plans within the industry, including Medicare and Medicaid.

### **PRINCIPLE #8**

While employer self-funded plans are not regulated by state insurance commissioners, we call upon these employers to adopt the Cancer Patients' Bill of Rights and enforce it with any insurer that administers their plan.

# APPENDIX: PROTON THERAPY FACTS

**P**roton therapy is a medically necessary, FDA-cleared treatment for cancer patients. In the early days of proton therapy, because of technological limitations, the therapy was used for a limited number of conditions and demonstrated considerable value for pediatric populations, patients with tumors affecting the brain and skull-base, paranasal sinuses, eye tumors and arteriovenous malformations. With technological advances, the data show considerable promise and improvement in side effects of patients with cancers of the breast, esophagus, liver, lung and head and neck.

**For many cancer patients, proton therapy is prescribed by their physician and is the optimal and most effective treatment option. Studies have shown that proton therapy can help increase survival, reduce the risk of secondary cancers, result in fewer acute and long-term conditions as well as debilitating short-term side effects and improve quality of life for individuals undergoing cancer treatment.**

Outlined below are key research findings that underscore the many benefits of proton therapy for certain cancer patients:

## SECONDARY CANCERS

- When compared with photon radiation, proton therapy allows for an increased dose of radiation to a cancerous tumor while decreasing the dose to adjacent critical structures. The use of proton radiation therapy has not been associated with an increased risk of secondary malignancies compared with photon therapy.<sup>1</sup>
- Compared with intensity-modulated radiation therapy (IMRT), proton therapy can reduce the risk of a patient developing a secondary cancer by 26 to 39 percent.<sup>2</sup>

## HEAD AND NECK CANCERS: CANCERS OF THE OROPHARYNX NASOPHARYNX AND SKULL-BASE CHORDOMAS

- With proton therapy, unnecessary radiation doses can be avoided in head and neck cancer patients, resulting in significant improvement in quality of life during and after treatment.<sup>3</sup>
- Patients with cancers of the oropharynx and nasopharynx had less swallowing dysfunction following proton therapy, and were approximately 60 percent less likely to need a feeding tube.<sup>4</sup>
- Proton therapy reduces the rates of feeding tube dependency and severe weight loss for patients with oropharyngeal cancers and improves survival for patients with paranasal and nasal cavity malignancies.<sup>5</sup>

- Proton beam therapy is “an effective treatment modality for skull base chordomas.”<sup>6</sup>
- Compared with historical photon therapy data, proton therapy results in better local control and overall survival treatments for patients with chordomas and chondrosarcomas of the spine.<sup>7</sup>

## **BREAST CANCER**

- Proton therapy after mastectomy or breast-conserving surgery significantly reduces cardiac exposure to radiation<sup>8</sup> and improves target coverage for the internal mammary nodes, which may positively impact longterm survival in breast cancer patients.<sup>9</sup>

## **NON-SMALL CELL LUNG CANCER (NSCLC)**

- Virtual clinical studies have shown that, compared with photon-based radiation therapy, proton therapy can spare critical structures of excess radiation, particularly the heart, lungs, esophagus and spinal cord.<sup>10</sup>
- One study found that among NSCLC patients, those who received proton therapy reported less severe patient-reported symptoms such as fatigue, pain, drowsiness and lack of appetite than those receiving IMRT or 3D Conformal Radiation Therapy (3DCRT).<sup>11</sup>
- Other studies of proton therapy patients have demonstrated promising clinical outcomes in reducing toxic effects compared to IMRT.<sup>12</sup> Another study found that patients with locally advanced NSCLC also demonstrated an “excellent overall survival rate with tolerable

toxicity” after undergoing proton therapy treatment with lower rates of toxicity than would be expected with photon therapy treatment.<sup>13</sup>

## **PEDIATRIC CANCER**

- Data show pediatric cancer patients benefit from reduced integral dose with protons compared with photons. Patients with tumors in the central nervous system, head and neck and some abdominal locations have a reduction of radiation dosage to normal tissues and potentially fewer late toxicities if treated with protons compared with photons.<sup>14</sup>

## **ESOPHAGEAL CANCER**

- In a study of nearly 450 patients with esophageal cancer, those who received proton therapy had fewer gastrointestinal and pulmonary toxicities than those receiving photon therapy.”<sup>15</sup>
- In patients with locally advanced esophageal cancer, proton therapy has been shown to be associated with improved survival rates compared to modulated radiation therapy.<sup>16</sup>
- Another study found that patients with esophageal cancer who underwent proton beam therapy treatment had significantly fewer postoperative complications and spent fewer days in the hospital compared to patients who underwent other types of radiation therapy.<sup>17</sup>

## LIVER CANCER

- In liver cancer, contemporary data for proton therapy are highly promising. In a recent phase II trial including a large number of patients with advanced liver disease, median progression-free survival was 36 months, with a 60 percent three-year progression-free survival rate for patients.<sup>18</sup>
- In a randomized trial of transarterial chemoembolization (TACE) versus proton therapy, proton therapy was superior on multiple metrics. For example, the total hospitalization days within 30 days of the procedures for the entire cohort was 166 versus 24, in favor of protons.<sup>19</sup>

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  - 2 Fontenot JD, Lee AK, Newhauser WD. Risk of secondary malignant neoplasms from proton therapy and intensity-modulated x-ray therapy for early-stage prostate cancer. *Int J Radiat Oncol Biol Phys* 2009;74:616-22
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## DELAY AND DENIAL DATA INFORMATION

Several U.S. proton therapy centers provided data to the Alliance for this report. The data represents the experience of 1,100 cancer patients whose physicians requested authorization for proton radiation therapy. These patients were:

1. Ages 18-64;
2. Insured by commercial payers (i.e., not Medicare or Medicaid);
3. Diagnosed with various forms of cancer that benefits from targeted proton radiation therapy, including: breast, head and neck, central nervous system, gastro-intestinal, sarcoma, thoracic and others. Prostate cancer was not included;
4. Diagnosed and/or treated between 2016-2018.



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